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Application Number	09/904,692
Filing Date	July 13, 2001
First Named Inventor	Raymond F. Jakubowicz
Art Unit	1743
Examiner Name	Lyle A. Alexander
Total Number of Pages in This Submission	28
Attorney Docket Number	961_002RCE

ENCLOSURES (check all that apply)

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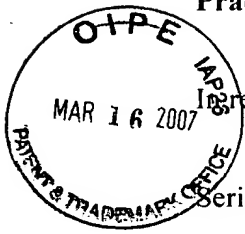
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PTO/SB/17 (07-06)



Practitioner's Docket No.: 961_002RCE

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Raymond F. Jakubowicz et al.

Serial No.: 09/904,692

Art Unit: 1743

Filed: July 13, 2001

Examiner: Lyle A. Alexander

For: TANDEM INCUBATOR FOR CLINICAL ANALYZER

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Cheryl M. Nichols
(Cheryl M. Nichols)

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

BRIEF ON APPEAL

Sir:

This Brief is in furtherance of the Notice of Appeal, filed in this case on January 19, 2007, and supports the appeal to the Board of Patent Appeals and Interferences from the final rejection, dated September 28, 2006, in the above-captioned application. As noted, Appellant filed the Notice of Appeal on January 19, 2007, and now submits the Brief pursuant to 35 U.S.C. §134 and 37 C.F.R. §§1.191 and 41.31 et seq. The fees required under 37 C.F.R. §41.20, and any required petition for extension of time for filing this brief and fees therefore, are dealt with in the accompanying Transmittal of Appeal Brief.

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I. REAL PARTY IN INTEREST

(37 C.F.R. §41.37(c)(1)(i))

The real party in interest is Ortho-Clinical Diagnostics, Inc., the Assignee of Record (see Reel 012573/Frame 0398).

II. RELATED APPEALS AND INTERFERENCES

(37 C.F.R. §41.37(c)(1)(ii))

Appellant is unaware of any other prior and pending appeals, interferences or judicial proceedings which may be related to, directly affect, or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

(37 C.F.R. §41.37(c)(1)(iii))

A. Total Number of Claims in Application

Claims in the application are: Claims 1-71.

B. Status of all the Claims

1. Claims cancelled: Claims 1, 2, 4, 5, 23-55, 60, 61, 67-71.
2. Claims withdrawn from consideration but not cancelled: None.
3. Claims objected to: None.
4. Claims allowed or confirmed: None.
5. Claims rejected: Claims 3, 6-22, 56-59, 62-66.

C. Claims on Appeal

The claims on appeal are: Claims 3, 6-22, 56-59 and 62-66.

IV. STATUS OF AMENDMENTS

(37 C.F.R. §41.37(c)(1)(iv))

No Amendments were filed subsequent to final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

(37 C.F.R. §41.37(c)(1)(v))

Generally, the claimed subject matter is directed to apparatus and methods for use in a clinical analyzer for the processing of patient samples. Appellant's systems and methods allow for increased versatility and improved efficiency in the processing of dry slide elements used in a clinical analyzer.

Specifically, the Appellant's claims describe systems and methods that contemplate an incubator having a first or inner ring and a second or outer ring, see page 11, lines 8-10 of the application, in which each of the inner and outer rings include pluralities or arrays of slide element receiving areas that are circumferentially disposed; see page 11, lines 11-14 of the application. Each of the pluralities of slide element receiving areas or stations is radially adjacent to one another within a common horizontal plane. See, for example, Fig. 7, of the application. The incubator is further defined by a first drive mechanism, see page 12, lines 1-7 of the application, that drives at least one of the inner and outer rings rotationally about an axis within the horizontal plane. At least two second drive mechanisms selectively move slide elements radially exclusively within the common horizontal plane into and out of the incubator, as well as between the first and second pluralities of slide element receiving areas, see page 14, lines 6-11 of the application. Each of the at least two second drive mechanisms includes at least one reciprocating pusher blade assembly for loading slide elements into one of the inner ring and outer ring and between the inner and outer rings. See page 14, lines 12-17, page 15, lines 1-22 and

Figs. 10-12 of the application.

Thus, with regard to Claim 62, a sequential random incubator for use in a clinical analyzer is recited. The incubator comprises an inner ring and an outer ring in which the outer ring includes a first plurality of circumferentially disposed slide element receiving areas and the inner ring includes a second plurality of circumferentially disposed element receiving areas, see page 11, lines 11-14. Each of the first and second pluralities of slide element receiving areas is radially adjacent to one another on a common horizontal plane. See, for example, Fig. 10.

The herein claimed incubator further includes at least one first drive mechanism to drive at least one of the inner ring and outer ring about at least one axis within the common horizontal plane, see page 12, lines 1-7. The incubator further includes at least two second drive mechanisms used to selectively move slide elements radially with respect to the slide element receiving areas of the inner and outer rings, as well as into and out of the incubator, see page 14, lines 6-11. Claim 62 further specifies that each of the at least two second drive mechanisms includes at least one reciprocating pusher blade assembly for loading slide elements into one of the inner and outer rings and for moving slide elements therebetween, see page 14, lines 12-17 and page 15, lines 1-22.

Independent Claim 63 recites a method of incubating and reading test slide elements using a sequential random incubator in a clinical analyzer. The incubator, as recited in independent Claim 63, comprises an inner ring and an outer ring in which the outer ring includes a first plurality of circumferentially disposed slide element receiving areas and the inner ring includes a second plurality of circumferentially disposed slide element receiving areas, see page 11, lines 11-14 and Fig. 10. Each of the pluralities of slide element receiving areas is radially adjacent to one another within a common horizontal plane; see, for example, Fig. 7. The method includes the steps in which at least one slide element is radially loaded into an empty slide element receiving

area; see page 14, lines 12-17. At least one of the inner and outer rings is then rotated within the horizontal plane and subsequently, the at least one slide element is moved radially from the initial slide element receiving area to another slide element receiving area in order to improve the throughput of the incubator, see page 15, lines 1-22. According to this claim, it is specified that the radially loading and moving steps are performed using at least two reciprocating pusher blade assemblies disposed in relation to the incubator and within the common horizontal plane, see Figs. 10-12, as well as page 15, lines 14-22.

As noted in dependent Claim 66, a plurality of second drive mechanisms can, for example, be circumferentially disposed in relation to the incubator to selectively load and shift slide elements between slide element receiving areas, see page 15, lines 4-22 and Figs. 10-12.

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

(37 C.F.R. §41.37(c)(1)(vi))

The grounds of rejection presented for consideration in this Appeal are:

1. Claims 3, 6-22, 56-59 and 62-66 stand rejected under 35 U.S.C. §102(b) as being anticipated by Jakubowicz et al (U.S. Patent No. 5,244,633).
2. Claims 3, 6-22, 56-59 and 62-66 stand rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement.

VII. ARGUMENT

(37 C.F.R. §1.192(c)(7))

A. Claims 3, 6-22, 56-59 and 62-66 cannot be anticipated based on Jakubowicz, et al.

The standards for successfully maintaining an anticipation rejection under the Statute require that “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”, as noted in MPEP 2131.01, quoting Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987).

Jakubowicz et al. (hereinafter referred to as Jakubowicz) refers to an incubator that is used in a clinical analyzer. A plurality of cup-shaped liquid-containing cuvettes 14 are held on one of two independently rotatable rings 52, 54 of the incubator. See, for example, Figs. 2 and 3 of Jakubowicz.

Claims 62 and 63 are the sole independent claims in the application. If the independent claims are not anticipated, then the dependent claims also cannot be anticipated in that dependent claims merely add limitations. Therefore, the discussion provided relates primarily to these independent claims.

Turning first to Claim 62, this apparatus claim specifically recites first and second drive mechanisms that enables rotation of the inner and outer rings of the incubator with regard to at least one first drive mechanism and radial movement with regard to movement of slide elements relative to the incubator along a horizontal plane with regard to at least two second drive

mechanisms. Moreover, each of the at least two second drive mechanisms according to this claim include at least one reciprocating pusher blade assembly for radially loading slide elements into one of the inner ring and the outer ring and for radially moving slide elements between the inner ring and outer ring.

Jakubowicz fails to include a second drive mechanism that loads slide elements into one of the inner and outer ring of the incubator. As noted above, the cited reference specifically relies upon the storage and movement of a plurality of cup-shaped cuvettes into and through the incubator and not slide elements. The Examiner believes that there is no structural difference between the slide elements and the cuvettes for purposes of this claim. Appellant respectfully disagrees. A slide element is referred to within the text of the present specification with reference to U.S. Patent No. 3,992,158 to Przybylowicz et al for purposes of a dry chemistry system. See the application at page 7, lines 18-20 and page 8, lines 21-23. Though there are differences noted at page 7 concerning various types of slide elements for test purposes, there are common features pertaining to each that allow these containers to be utilized as would be known to those of sufficient skill in the field with regard to a “dry” chemistry system. The cup-shaped cuvettes that are used by Jakubowicz, on the other hand, would suggest a different geometry to one of sufficient skill, these cuvettes being useful for a “wet” chemistry system as opposed to a “dry” system.

In relation to more direct structural differences that distinguish the cited reference from the claimed invention, a closer reading of Jakubowicz indicates that each of the cup-shaped cuvettes are not radially loaded into the incubator. See Jakubowicz at col. 4, lines 29-31 and 43-44 in which a pusher means 43, shown in Fig. 2, is used to vertically loads each of the cuvettes into the incubator. As such, this reference fails to teach or recite a second drive mechanism that is used to radially load any form of test element, whether cuvettes or slide elements, into one of the inner

ring and the outer ring. On the other hand, Claim 62 specifically recites second drive mechanisms that are used to load a slide element, not a cup-shaped cuvette, into one of the inner ring and the outer ring and also between the inner ring and outer ring to thereby selectively move the slide elements between adjacent slide element receiving areas in combination with a first drive mechanism that rotates at least one of the inner and outer rings in order to improve throughput of test elements through the incubator. The advantage achieved by permitting all of the second drive mechanisms to be horizontally planar is that the test slide elements can effectively be loaded and shifted synchronously.

In addition, at least two second drive mechanisms are required, according to Claim 62, in order to radially move the slide elements both into and out of the incubator, as well as between the inner and outer rings. Jakubowicz, on the other hand, merely describes a single horizontal drive mechanism; see col. 6, lines 60-65 of the cited reference. Though two push rods are described for purposes of this mechanism, these rods are required as part of a single mechanism, see col. 6 line 68-col. 7, line 9. In summary and with regard to Claim 62, this reference fails to teach or describe even one second drive mechanism that is used to radially load slide elements, or in fact any container, into the incubator. Jakubowicz also fails to provide any teaching to multiple second drive mechanisms for moving slide elements between radially adjacent slide element receiving areas. Because numerous essentially claimed features are not found in the cited reference, it is believed that an anticipation rejection cannot be maintained against Claim 62.

As to Claim 63, Jakubowicz fails to teach a method in which a slide element is radially loaded into an empty slide element receiving area of an incubator using a reciprocating pusher blade assembly disposed in relation to one of the inner ring and the outer ring. As noted above, Jakubowicz relates to an incubator that utilizes cup-shaped cuvettes, see Fig. 2, and relies upon pusher means 43 to vertically and not radially load each cup-shaped cuvette into an empty portion

of a ring 52, 54, see col 4, lines 29-32, col 4, lines 41-47 and Fig. 2 of Jakubowicz. Jakubowicz also fails to include at least two reciprocating pusher blade assemblies that are disposed in relation to the inner ring and the outer ring to permit radial movement and radial loading steps of the method to be performed. Referring to Fig. 13-16, and col 6, lines a pair of push rods 202, 204 are disclosed. However, as best understood, each of the push rods appear to constitute a single drive mechanism to enable radial movement between the rings and to unload a cup shaped cuvette with regard to a dump station.

Because several recited features of independent Claim 63 do not appear in the cited reference, there can be no anticipation under the Statute. Because each of the dependent claims on appeal include additional features, it is believed these arguments apply therefor. Therefore, it is respectfully requested that the Examiner's rejection be reversed.

Appellant would further like to point out that the Examiner has not commented on the dependent claims of the application in spite of the fact that numerous amendments have been made to the claims. To that end, Appellant refers the Board to Appellants' response of July 11, 2006 that drew the final Action being appealed. As noted therein, a number of the dependent claims, in addition to Claims 62 and 63, were extensively amended, yet not commented upon by the Examiner. Though the Examiner commented upon Appellant's previous remarks, no discussion in the rejection has been made concerning the subject matter of previously amended claims with regard to the cited prior art. To that end, it is clear the Examiner has not wholly considered the dependent claims, for example Claim 66. Nowhere does Jakubowicz teach or remotely suggest the notion of providing a plurality of circumferentially disposed pusher blade assemblies, yet the Examiner has not commented thereupon. In this sense, it would appear on the record that examination of the application is therefore incomplete.

B. Claims 3, 6-22, 56-59 and 62-66 comply with the written description requirement pursuant to 35 U.S.C. §112, first paragraph.

The argument stated at page 2 of the final Action is that Appellants' July 11, 2006 amendments, specifically "at least two second drive mechanisms..." as recited in Claims 62, 63, is not taught in the original disclosure. Therefore, it is believed the entirety of the Examiner's ground is a lack of support for these recited drive mechanisms. Appellant disagrees and maintains that such support is repletely evident. Referring to page 3, lines 17-28, discussion is made of the use of reciprocating pusher blades to transfer slide elements between radial positions on the inner and outer rings. Moreover, at page 3, lines 23-28, discussion is made as to the use of reciprocating pusher blades for both loading of elements into the incubator, as well as the addition disposition of pusher blades about the periphery of the incubator in order to "shift the radial position of the test (slide) elements following initial placement...to increase the efficiency and throughput of the overall assembly." In the final Action, the Examiner remarks concerning "a third drive mechanism". This third drive mechanism is described at page 13 of the application with regard to a pivoting shuttle 175 used in conjunction with a reciprocating pusher blade assembly 188 (one of the second drive mechanisms) "which permits a loaded slide element 144 to be shuttled to a wash position 172, as shown in Fig. 6, relative to a wash metering system (not shown)." See page 13, lines 16-19.

Reference is also made herein to page 14, lines 6-17 with regard to the disposition of multiple reciprocating pusher blade assemblies, as well as Figs. 10-12. Still further disclosure is provided at page 15, lines 1-22. To that end, it is believed that the present application more than adequately meets the written description requirement under Section 112 and that this rejection should be withdrawn.

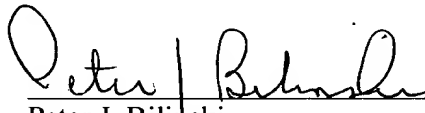
VIII. CONCLUSION

For the foregoing reasons, Appellant respectfully requests reversal of the Examiner's rejections of claims.

The Commissioner is hereby authorized to charge any additional fees associated with this submission, or to credit any overpayment to Deposit Account 50-0289.

Respectfully submitted,

Dated: March 16, 2007


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APPENDIX OF CLAIMS

(37 C.F.R. §41.37(c)(1)(viii))

The text of the claims involved in the appeal are:

3. (Previously Presented) An incubator as recited in Claim 62, wherein each of said inner and outer rings are supported for rotation by said at least one first drive mechanism about a central axis of an incubator housing.

6. (Previously Presented) An incubator as recited in Claim 3, wherein at least one of said first and second pluralities of circumferentially disposed slide element receiving areas includes at least two radially adjacent slide element receiving stations disposed in said areas wherein said at least one reciprocating pusher blade assembly of one of said second drive mechanisms is capable of can selectively radially moving move said at least one slide element between at least said at least two adjacent slide element receiving areas.

7. (Previously Presented) An incubator as recited in Claim 6, including at least one read station disposed in relation to one of said inner and outer rings, such that said at least one first drive mechanism can rotate one slide element receiving area into a read position, said at least one reciprocating pusher blade assembly enabling a slide element to be selectively and radially

moved from a radially adjacent slide element receiving area into the read position.

8. (Original) An incubator as recited in Claim 7, including a dump station radially adjacent said read station.

9. (Previously Presented) An incubator as recited in Claim 7, wherein said read station includes a device capable of detecting an optical property of a test slide element.

10. (Original) An incubator as recited in Claim 9, wherein said device is a reflectometer .

11. (Previously Presented) An incubator as recited in Claim 62, wherein said at least one reciprocating pusher blade assembly of said at least two second drive mechanisms can selectively and radially removes remove at least one slide element from said incubator for later reinsertion therein.

12. (Previously Presented) An incubator as recited in Claim 7, wherein said read station includes a device capable of measuring an electrical property of a slide element.

13. (Original) An incubator as recited in Claim 12, wherein said device is an electrometer.

14. (Previously Presented) An incubator as recited in Claim 62, including a plurality of dry slide elements, each of said dry slide elements having a volume of a patient sample fluid

metered thereupon prior to entry into said incubator.

15. (Previously Presented) An incubator as recited in Claim 6, wherein said at least one reciprocating pusher blade assembly of said at least two second drive mechanisms radially shuttles slide elements into and out of said incubator housing.

16. (Previously Presented) An incubator as recited in Claim 15, wherein said at least one reciprocating pusher blade assembly is at least two of said at least two second drive mechanisms are circumferentially disposed immediately adjacent in relation to at least one of said first inner ring and said second outer ring.

17. (Previously Presented) An incubator as recited in Claim 15, wherein said at least one reciprocating pusher blade assembly of each of said at least two second drive mechanisms is disposed in relation to said incubator housing to shuttle at least one slide element into at least one slide element receiving station.

18. (Previously Presented) An incubator as recited in Claim 15, wherein said at least one reciprocating pusher blade assembly of each of said two second drive mechanisms is capable of shuttling can move at least two radially disposed slide elements into radially adjacent slide element receiving areas or receiving stations simultaneously.

19. (Previously Presented) An incubator as recited in Claim 15, including a supply of stacked slide elements, at least one said reciprocating pusher blade assembly second drive mechanism being disposed adjacent to said slide element supply.

20. (Previously Presented) An incubator as recited in Claim 62, wherein said at least one first drive mechanism includes a drive belt drive wrapped about the periphery of at least one of said inner and outer rings.

21. (Previously Presented) An incubator as recited in Claim 62, wherein said inner and outer rings are independently driven relative to one another by said at least one first drive mechanism.

22. (Previously Presented) An incubator as recited in Claim 62, wherein at least two load positions of a slide element receiving area differ in height relative to one another.

56. (Previously Presented) A method as recited in Claim 63, including the additional steps of:

reading a first slide element which has been rotated into alignment with a read station;
radially driving an adjacent second slide element into alignment
with said read station using at least one of said reciprocating pusher blade assemblies; and
reading said second slide element.

57. (Previously Presented) A method as recited in Claim 56, including the step of dumping each of said slide elements from said inner ring after said reading steps.

58. (Currently Amended) A method as recited in Claim 57, including the step of radially loading at least one slide element from the outer ring into said inner ring using

at least one reciprocating pusher blade assembly after said dumping step.

59. (Previously Presented) A method as recited in Claim 58, wherein said loading step includes the step of simultaneously radially shuttling at least two adjacent test slide elements into radially adjacent slide element receiving areas.

62. (Previously Presented) A sequential tandem incubator for use in a clinical analyzer, said incubator comprising:

an inner ring and an outer ring, said outer ring including a first plurality of circumferentially disposed slide element receiving areas and said inner ring including a second plurality of circumferentially disposed slide element receiving areas, each of said first and second pluralities of slide element receiving areas being radially adjacent to one another on a common horizontal plane;

at least one first drive mechanism for driving at least one of said inner and outer rings rotationally about at least one axis and within said common horizontal plane; and

at least one two second drive mechanism mechanisms for selectively moving slide elements exclusively in a radial direction exclusively within along said common horizontal plane into and out of said incubator and between said first and second plurality of said circumferentially disposed slide element receiving areas in order to increase throughput of said incubator, each of said at least one two second drive mechanism mechanisms including at least one reciprocating pusher blade assembly for loading slide elements into one of said inner ring and said outer ring and for moving slide elements between said inner ring and said outer ring.

63. (Previously Presented) A method of incubating and reading test slide elements

using a sequential random incubator in a clinical analyzer, said sequential random incubator comprising an inner ring and an outer ring, said outer ring including a first plurality of circumferentially disposed slide element receiving areas and said inner ring including a second plurality of circumferentially disposed slide element receiving areas, each of said first and second pluralities of slide element receiving areas being radially adjacent to one another within on a common horizontal plane, said method comprising the steps of:

radially loading at least one slide element into an empty slide element receiving area using a reciprocating pusher blade assembly disposed in relation to one of said inner ring and said outer ring;

rotating at least one of said inner and outer rings within along the common horizontal plane; and

moving said at least one slide element radially between said first and second pluralities of radially adjacent slide element receiving areas of said incubator along within said common horizontal plane so as to improve the throughput of said incubator, wherein said radially loading and said radially moving step is steps are performed using at least two reciprocating pusher blade assembly assemblies disposed in relation to said inner ring and said outer ring incubator and within said common horizontal plane.

64. (Previously Presented) An incubator as recited in Claim 62, wherein a plurality of second drive mechanisms reciprocating pusher blade assemblies are disposed at predetermined circumferential locations adjacent to said inner and outer rings, each of said second drive mechanisms including a reciprocating pusher blade assembly.

65. (Previously Presented) An incubator as recited in Claim 62, wherein at least one

reciprocating pusher blade assembly is radially disposed on the interior of said inner ring.

)

66. (Previously Presented) An incubator as recited in Claim 64, wherein each of said plurality of second drive mechanisms reciprocating pusher blade assemblies are circumferentially disposed at predetermined locations about said outer ring, wherein the reciprocating pusher blade assemblies of at least two of said plurality of second drive mechanisms can load and unload at least one slide element in relation to said incubator and can further radially move at least one slide element between slide element receiving areas as the inner ring and outer ring are rotated by the first drive mechanism in order to move each of said first and second pluralities of slide elements receiving areas being movable into registration with said second drive mechanism capable of moving radially through each of said inner and outer rings.

APPENDIX OF EVIDENCE

(37 C.F.R. §41.37(c)(1)(ix))

Appellant herein attaches a copy of original U.S. Application Serial No. 09/904,692 as filed on July 13, 2001, as item A to this Appendix;

Appellant further refers to a copy of the July 11, 2006 response to non-final Action filed by Appellant, attached herewith, as item B to this Appendix;

Appellant further refers to a copy of final Office Action having a mailing date of September 28, 2006, attached herewith, as item C to this Appendix;

Appellant further refers to a copy of cited reference U.S. Patent No. 5,244,633 to Jakubowicz et al., attached herewith, as item D to this Appendix; and

Appellant further refers to a copy of cited reference U.S. Patent No. 3,992,158 to Przybylowicz et al., attached herewith, as item E to this Appendix.

Copies of the preceding documents are relied upon in Appellant's argument and in prosecution of the application, for the Board's convenience.

- A. Original application U.S. Serial No. 09/904,692-as filed on July 13, 2001.
- B. July 11, 2006 response to non-final Action filed by Appellant.
- C. Final Office Action having a mailing date of September 28, 2006.
- D. Jakubowicz et al. (U.S. Patent No. 5,244,633)
- E. Przybylowicz et al. (U.S. Patent No. 3,992,158)

RELATED PROCEEDINGS APPENDIX

(37 C.F.R. §41.37(c)(1)(x))

There are no related proceedings.

TANDEM INCUBATOR FOR CLINICAL ANALYZER

Field of the Invention

The invention relates to the field of analytical sample testing and in particular to a sequential tandem incubator for a clinical analyzer.

Background of the Invention

Clinical analyzers typically include at least one incubator that is used for the processing of patient samples. A typical "dry" chemistry incubator, for example, is defined by a rotor assembly that includes a single rotatably driven ring having a plurality of circumferentially disposed load stations. Each of the load stations are sized to accommodate a dry element onto which a quantity of patient sample can be metered.

According to at least one version of a dry-type incubator, the slide elements are supplied one at a time to a metering station which is adjacent to the incubator. After sample fluid has been metered, the slide element is shuttled or otherwise introduced into an empty load station of the incubator, such as through use of a reciprocating pusher blade as the rotor assembly advances the next empty load station into position for receiving the next metered slide element.

Various types of sample testing, including potentiometric, rate chemistry, and endpoint tests, may be required for any given patient sample, necessitating both different incubation intervals and test apparatus within the incubator. Therefore, scheduling for multiple types of patient sample tests will certainly and significantly affect the overall throughput of the device. Though several dedicated incubator assemblies could be provided within an analyzer as a potential solution to the throughput problem, there is an equally competing need in the field to keep the overall footprint of the clinical analyzer as small as possible.

Attempts have been made in order to improve the efficiency of incubator assemblies in general. For example, referring to Fig. 1 and as described by U.S.

U.S. Patent No. 5,523,056 to Miller, an incubator assembly 50 includes a pair of vertically stacked rotor assemblies 54,58, each of the rotor assemblies being accessible to a metering station (not shown) by means of an elevator that permits an additional number of dry slide elements to be accommodated. This vertical arranged stacking, according to the teachings of this reference, saves available space for the analyzer. Other attempts to improve efficiency have incorporated multiple read stations within the incubator assembly to handle the different types of tests that are required.

Summary of the Invention

It is a primary object of the present invention to overcome the above noted problems of the prior art.

It is another primary object of the present invention to increase the overall throughput of an incubator assembly without significantly increasing the size thereof.

It is yet another primary object of the present invention to provide an incubator assembly which does not require a multiple number of test read stations.

Therefore and according to a preferred aspect of the present invention, there is disclosed an incubator including an incubator housing having at least one load station for accommodating at least one test sample and at least one stationary read station which is disposed within the incubator housing. First drive means are provided for driving at least one of said at least one test sample and the load station in a first direction. The at least one load station includes at least two movable load positions which are arranged in a second direction, the second direction being substantially orthogonal to said first direction. Second drive means selectively drive at least one of said load positions and said at least one test sample accommodated therein in the second direction with respect to the at least one read station for reading said at least one test sample.

According to a preferred embodiment, the incubator includes a ring assembly including at least two concentric rings disposed within a housing.

Each of the concentric rings are preferably supported for rotation about a common center axis of rotation, and include a plurality of circumferentially disposed load stations. First drive means drives each of the load stations circumferentially about the axis of rotation in order to incubate test elements or sample containers, while a second drive means selectively and radially drives at least one of the test elements or sample containers or at least one corresponding load station in order to move one of the test elements or sample containers for analyte-correlated signal detection at a read station. More particularly, the second drive means moves or transfers at least one test element or sample container between a first load position and a second load position of a load station.

In a preferred embodiment, a read station is disposed with regard to one of the concentric rings such that a first test element or sample container can be read when the ring is rotated into alignment with the first test element. Following this read step, a second radially adjacent test element or sample container can be transferred by the second drive means into alignment with the read station for reading thereof.

According to a preferred embodiment, sample fluid is metered onto test elements and at least one reciprocating pusher blade serves as the second drive means to radially transfer at least one test element from one load position to an adjacent load position on the ring assembly for alignment with the read station. Each of the test elements can then be disposed of; that is, the test elements can be dumped from the incubator and new test elements can be added. In a preferred embodiment, a pair of test elements can be added to the incubator housing simultaneously using a single or multiple pusher blades. An additional number of pusher blades disposed about the periphery of the ring assembly can be used to shift the radial position of the test elements following initial placement within the incubator housing, as needed, in order to increase the efficiency and throughput of the overall assembly.

The incubator can also include third drive means for selectively and radially removing at least one test element or sample container from a load station of the ring assembly for later reinsertion therein.

According to a preferred embodiment, single read stations are provided for colorimetric and potentiometric sample testing, respectively, in which the slide elements can be transferred between concentric rings of the ring assembly. Furthermore, each of the concentric rings can be independently driven to further maximize efficiency and test scheduling.

According to a preferred aspect of the invention, there is disclosed an incubator for use in a clinical analyzer, said incubator comprising:

an incubator ring assembly supported for rotation about an axis of rotation, said ring assembly including a plurality of circumferentially defined load stations, each said load station having at least two adjacent radial load positions for receiving test elements or sample containers;

at least one read station for reading at least one test element or sample container at a read position:

first drive means operatively connected to said incubator ring assembly for rotating said ring assembly about said axis of rotation, said at least one said read station being disposed such that a first plurality of circumferentially disposed load positions can be selectively aligned with said read position; and

second drive means for radially moving a test element or sample container from at least one load position of a load station into the read position.

According to yet another preferred aspect of the present invention, there is disclosed a clinical analyzer comprising an analyzer housing and an incubator disposed within the analyzer housing. The incubator includes at least one load station for accommodating at least one test element or sample container and at least one read station. First drive means are provided for driving at least one of said at least one test element or sample container and said load station in a first direction, said at least one load station having at least two load positions arranged in a second direction, said second direction

being substantially orthogonal to said first direction; and second drive means for selectively driving at least one of said load positions and said at least one test element or other sample container accommodated therein with respect to said read station for testing said at least one test element or sample container.

According to yet another preferred aspect of the present invention, there is provided a method of incubating and reading test samples for a clinical analyzer, said incubator comprising at least one load station for accommodating at least one test element or sample container and a read station disposed within an incubator housing, the method comprising the steps of:

driving at least one of test element or sample container and said load station in a first direction, said at least one load station having at least two load positions arranged in a second direction, said second direction being substantially orthogonal to said first direction; and

selectively driving at least one said load station and said at least one test element or sample container accommodated therein in the second direction to locate at least one test element or sample container relative to said read station for reading said at least one test element or sample container.

An advantage of the present invention is that providing an incubator having concentric multiple ring components with adjacent radial load positions and a plurality of shuttle assemblies to permit the interchange of test samples between these positions increases the number of potential opportunities to schedule and efficiently perform multiple types of tests. As a result, the overall efficiency of the incubator is maximized and the overall throughput of an analyzer utilizing the incubator is increased.

It will be readily apparent from the discussion that follows that the incubator can include element receiving stations which can be driven using rotary or linear movement (a first direction) and radial or linear movement (a second direction) so as to maximize throughput with a minimum number of read stations.

Another advantage of the present invention is that the coordination of elements or sample containers which are incubated and tested is far more flexible and efficient than any previously known apparatus.

Yet another advantage is that the herein described incubator includes single read stations for performing potentiometric and colorimetric sample testing, respectively, thereby simplifying overall assembly and cost.

These and other objects, features, and advantages will become readily apparent from the following Detailed Description which should be read in conjunction with the accompanying drawings.

Brief Description of the Drawings

Fig. 1 is a partial top perspective view of an prior art incubator;

Fig. 2 is a simplified partial top view of the interior of an incubator made in accordance with a first embodiment of the present invention;

Fig. 3 is a partial top perspective view of an incubator assembly made in accordance with a second embodiment of the invention;

Fig. 4 is a partial top plan view of the incubator of Fig. 3;

Fig. 5 is the top plan view of the incubator of Fig. 4 with the inner ring of the ring assembly shown;

Fig. 6 is an enlarged view of the incubator of Fig. 4;

Fig. 7 is a partial top perspective view of the incubator of Figs. 3-6, including the metering station;

Fig. 8 is an enlarged partial top perspective view of the interior of the incubator of Figs. 3-7;

Fig. 9 is an enlarged top perspective view of the outer portion (ring removed) of the incubator of Figs. 3-8; and

Figs. 10-12 are pictorial illustrations of the incubator of Figs. 3-9 illustrating certain interrelationships between test sample loading and positioning of test samples within the incubator.

Detailed Description

The following description relates to specified embodiments of a sequentially loaded incubator made in conjunction with the present invention. Throughout the course of discussion, certain terms such as "inner", "outer", "lateral", "vertical", "horizontal", "upper", "lower" and the like are used to provide a frame of reference with regard to the accompanying drawings. These terms, however, except as indicated otherwise, should not be construed as limiting with regard to the herein claimed invention.

Also throughout the discussion, the term "element" is used in conjunction with a test sample. As defined herein, this term refers to dry slide elements as well as any other form of sample container. It will become readily apparent that this patent recites advantageous positioning of such containers in an incubator (rotary, linear or other) in order to improve throughput.

For purposes of background and to facilitate the following discussion, the following relates primarily to a "dry" incubator for use in a mainframe, desktop, or other type of clinical analyzer apparatus. The incubator according to each of the embodiments uses dry slide elements onto which a patient sample is metered. These slide elements are such as described in U.S. Patent No. 3,992,158 to Przybylowicz et al., the entire contents of which is hereby incorporated by reference. For purposes of the following discussion, there are generally two different types of slide elements, each relating to a form of patient sample testing that is required. A "potentiometric" slide element 140, Fig. 6, such as described by U.S. Patent Nos. 4,184,936 (Paul, et al.) and 4,214,968 (Battaglia, et al.), incorporated herein in their entirety, includes a pair of electrodes which can be interfaced with an electrometer or other suitable test apparatus capable of detecting an electrical property produced by a deposited test sample. A "colorimetric" slide element 144, Fig. 8, on the other hand, is capable of being read by a reflectometer or other suitable apparatus capable of detecting an optical property produced by or deposited onto the element through a read area provided on the slide element 144 which is aligned with an optical window of the testing device. Colorimetric slide elements are further

categorized as to the type of testing required. Endpoint testing, for example, requires only a single optical read after a predetermined incubation interval, while rate chemistry tests require multiple optical reads during various points of an incubation cycle.

Referring to Fig. 2, a first embodiment of an incubator assembly 10 illustrating a number of the essential concepts of the present invention is depicted in simplified form. Only the interior of the incubator assembly 10 is shown and described herein for reasons of clarity.

A linear array 12 of load stations 14 are arranged along a first direction 20. Each load station 14 includes a pair of slots or receiving areas 15, 17 that are arranged along a second direction 34. As is evident in Fig. 2, the second direction 34 is substantially perpendicular to the first direction 20. At least one row 13, 16 of receiving areas 15, 17 of the linear array 12 are capable of rectilinear movement along the first direction 20 through use of a drive belt (not shown) or other suitable conventional means. That is to say, each of the rows 13, 16 are capable of either independent or coupled movement along the first direction 20. A read station 26, is stationarily disposed at one end of the incubator 10, the read station including a testing device (not shown), such as a reflectometer or other suitable testing apparatus, which examines an optical or other property of a test element. The read station 26 is disposed beneath the movement plane of the linear array 12 of load stations 14.

Each load station 14 is sized to receive a pair of dry slide elements 18 such as those described in U.S. Patent No. 3,992,158 to Przybylowicz et al., the entire contents of which is hereby incorporated by reference. Each of the receiving areas 15, 17 of load station 14 includes respective openings 19 which correspond to a read area of a slide element 18 onto which a patient sample is first metered or dispensed at a metering station 32. As a slide element 16, 18 is moved into the read position 26, the opening 19 is aligned with the testing device. Adjacent the read station 26 and oppositely disposed along the second direction 34 are an eject slot or dump station 38 and a slide transferring device 25, respectively. Another slide element transferring device 23 is located at the

opposite end of the incubator 10 which is disposed in parallel with the slide transferring device 25 to permit movement of slide elements 18 along the second direction 34 as described herein.

In operation and according to this embodiment, a pair of slide elements 18A, 18B can be simultaneously loaded into the incubator 10 and into
5 respective empty receiving positions 15, 17 of a load station 14 using the slide transferring device 23. Each of the slide transferring devices 23, 25 shown include a reciprocating pusher blade, shown partially in Fig. 2, or other suitable means.

A first slide element 18A is shuttled to the metering station 32 from a
10 slide supply 31 and sample fluid is metered from a metering head (not shown). The specifics of metering a sample fluid onto a dry slide element is conventionally known and does not form an essential part of the invention. Therefore, no further discussion is required. Following metering, the slide
15 element 18A is advanced in the second direction 34 using a slide element transferring device (not shown), such as a reciprocating pusher blade, which engages the side edge of the element to advance the slide element to a staging position 33. In the staging position, the spotted slide element 18A is permitted to dry while a second slide element 18 is advanced from the slide supply 31 and is metered at the metering station 32. As noted, the details relating to
20 metering of a patient sample fluid and a metering mechanism are conventionally known and do not form a significant part of the present invention.

Following the metering of sample fluid onto each of the slide elements 18A, 18B, each of the slide elements are shuttled using a linear shuttle, a
25 linear pusher, belt or other conventionally known means into a load position adjacent the slide transferring device 23. Each of the slide elements 18B, 18A are then simultaneously loaded into respective receiving areas 15, 17 of the linear array 12.

Each of the rows of the linear array 12 are then advanced in the first direction 20 to advance additional empty receiving areas 15, 17 for loading of additional slide elements 18A, 18B in the same manner.

It should be noted that the only slide elements illustrated according to this embodiment are colorimetric slide elements for ease of illustration. As noted, these slide elements may require rate chemistry or endpoint tests. In brief, endpoint tests simply require a single optical read at the conclusion of an incubation interval while rate chemistry tests require multiple read operations during a separate incubation interval. Therefore, for purposes of the herein described invention, the slide elements designated as 18A may require either rate chemistry or endpoint chemistry tests and are loaded into row 16 of the linear array 12, while the slide elements designated 18B require end point and are positioned into the row 13.

The linear array 12 is reciprocated along the first direction 20, thereby permitting the slide element 18A to be read at the read station 26 an appropriate number of times. Following the final required read, the slide transferring device 25, such as a slide pusher blade, advances the slide element 18B into the read station 26, and shuttles the slide element 18A into the eject slot 38 for disposal. Depending on the tests required on the slide element 18B, the slide transferring device can again be used to displace the slide element 18B following the read to the eject slot 38 or the slide element 18B may remain for further testing and incubation. As a result, either one or two empty slots will be created.

It will be readily apparent that variations of this apparatus are possible. For example an additional read station could be provided including an electrometer for testing potentiometric slide elements. According to another alternate design, slide transferring device 23 could be positioned adjacent to slide transferring device 25, in order to fill empty load positions more efficiently.

It should be further noted that the above assembly, and others described herein, also may not be limited to utilization of dry slide elements; for example,

liquid test samples could be retained within test receptacles (not shown) and moved relative to a read station which for example includes a spectrophotometer (not shown) or other apparatus. Therefore, and despite the fact "elements" are recited in the following discussion and are claimed as such it should be noted that as noted the term elements implies slide elements as well as other sample containers.

Referring to Figs. 3-12, an incubator 100 in accordance with a preferred second embodiment of the invention includes a ring assembly 104 having a pair of concentric rings; namely, a first or inner ring 108 and a second or outer ring 112. Each of the inner and outer rings 108, 112 include a plurality of circumferentially spaced incubation positions.

According to this embodiment, the inner ring 108 is defined by a circular platen consisting of an array of pairs of radially adjacent slide element positions 116, 118, while the outer ring 112 includes a single circular array of slide element positions 122. A plurality of circumferential load stations are therefore defined, each load station being made up of an inner slide element position 116 and a middle or intermediate slide element position 118 each provided on the inner ring 108, as well as an outer slide element position 122 provided on the outer ring 112. A total of thirty-six (36) slide element positions are provided for each ring 108, 112, though it should be readily apparent that this parameter can easily be varied depending on the application.

Each of the inner and intermediate slide element positions 116, 118 defined by the inner ring 108 include a through opening 111 that permits read access by a reflectometer or other device capable of detecting an optical property of a test sample. The reflectometer 153, Fig. 7, is located beneath the inner ring 108 at an inner read station 150 as described below. According to this specific embodiment, no openings are provided for any of the outer slide element positions 122 of the outer ring 122, for reasons which will become apparent below.

A cover 126 is provided for the ring assembly 104 as partially shown in Fig. 3. The cover 126 provides thermal insulation to aid in temperature control of the interior of the incubator 100.

According to the present embodiment, the inner ring 108 and the outer ring 112 are each independently driven about a common center axis of rotation. As noted previously, the inner ring 108 is a single circular plate-like member which is driven by a belt drive 130, while the outer ring 112 is rotated onto a circular track 138, Fig. 9, using a gear drive. Each of the rings 108, 112 are peripherally supported by a set of V-bearings 134, as partially shown in Figs. 7 and 9, the incubator further including a hot plate 105 onto which each ring 108, 112 is mounted. The hot plate includes, for example, circular track 138, Fig. 9. It should be pointed out that the specific driving mechanisms for each of the rings 108, 112 of the herein described ring assembly 104 do not in and of themselves form an essential part of the present invention. That is to say, a number of different drive mechanisms could be substituted. Providing independent driving capability of each of the inner and outer rings 108, 112, however, is an important aspect of the invention, in that greater flexibility in the loading and shuttling transfer of slide elements 140, 144 into and between each of the slide element positions 116, 118, 122 is provided. This loading and shuttling of slide elements into and within the incubator 100 will be described in greater detail below.

A single pair of read stations 150, 160, Figs. 4,7, are provided for the incubator 100. An inner read station 150, includes a reflectometer 153, partially shown in Fig. 7, which is stationarily located beneath a predetermined circumferential position 154 relative to the inner ring 108 so as to be aligned with the array of rotatably movable inner slide element positions 116. The inner read station 150 therefore permits the reading of either rate chemistry or endpoint colorimetric slide elements 144 at the read location 154 through the opening 111 of an aligned inner slide element position 116. Details relating to the specific operation of the reflectometer 153 and the reading of test elements in general are commonly known in the field, such as described in U.S.

Patent No. 5,034,091, the entire contents of which are herein incorporated by reference.

An outer read station 160 is also provided which is radially adjacent to the outer ring 112. More specifically, the read station 160 is immediately adjacent to each of the outer slide element positions 122, the read station also being positioned at a predetermined circumferential position 164. As detailed below, an electrometer 163 (partially shown in Fig. 4) is provided at the outer read station 160 which allows selective access to a potentiometric slide element 140 after a predetermined incubation time when an element reaches the outer read station 160.

In addition to the inner and outer read stations 150, 160 and as shown in Figs. 3-6, 8 and 9, the herein described incubator 100 also includes a wash module 170 located within the inner periphery of the inner ring 108 to permit immuno-rate test capability. The wash module 170 includes an entrance slot 176 that is aligned with a slide pusher blade assembly 188, thereby permitting a slide element 144 to be loaded into the wash station 170 directly from the rotor assembly 104. The wash station 174 further includes a pivoting shuttle assembly 175 which permits a loaded slide element 144 to be shuttled to a wash position 172, as shown in Fig. 6, relative to a wash metering system (not shown) which performs washing thereof. The washed slide element 144 can then be shuttled back to its input position such that the slide element can be transferred back into the inner ring 108 by means of an internal pusher blade assembly 178.

Slide or evaporator caps 174, 179 some of which are partially depicted in Figs. 7 and 8, are provided for all slide positions 116, 118, 122, within the incubator 100, thereby providing evaporation and thermal control for each slide element 140, 144. Details relating to the general operation and function of evaporator caps in a clinical analyzer incubator, including the raising of same to load and unload same into and out of the housing through a cap holder 177, are generally known in the field, as described for example in U.S. Patent No. 5,034,191, to Porte, and U.S. Patent No. 4,963,333 to Shaw, et al.,

incorporated herein in their entirety by reference and therefore do not form an essential part of the claimed invention. For reasons described below, evaporator caps 179 used for potentiometric slide elements 140 are provided for each of the outer slide element positions 122 while evaporator caps 174 used for colorimetric slide elements 144 are provided for each of the slide element positions 116, 118 of the inner ring 108.

In order to effectively shuttle any of the slide elements 140, 144 both into and within the herein described incubator 100, a series of slide element transferring devices are provided.

According to this specific embodiment, and as shown in Figs. 3, 5-7, and 10-12, a total of five slide transferring devices 180, 183, 188, 192, 194 are provided in relation to a metering station 196.

Though shown only pictorially in Figs. 10-12, one slide transferring device 183 is located directly within the confines of a metering station 196 in order to initially shuttle a metered slide element, either a potentiometric or colorimetric slide element 140, 144, into the incubator rotor assembly 104 from a slide cartridge. The slide transferring device 183 operates in a manner which is commonly known, preferably using a reciprocating pusher blade.

The metering station 196 includes a metering head 198 which is disposed along the length of a metering rail 210, Figs. 10-12. A metering mechanism partially shown pictorially in Figs. 10-12 permits a patient sample to be delivered along the metering rail 210 from a sample container (not shown) using a proboscis and a disposable metering tip (also not shown) so as to dispense/meter sample onto a slide element 140, 144 provided from a slide supply 204. According to this embodiment, the slide supply 204 retains a plurality of vertically disposed sample cartridges (not shown) which are loaded into a carousel beneath the incubator 100. In a manner commonly known, the slide elements are incremented one at a time to the metering head 198 and are then shuttled into the outer ring 112 of the incubator 100. A series of bar code readers 206 are disposed in relation to the slide supply 204 in order to properly identify the slide elements that are loaded into the incubator 100.

Three (3) of the remaining slide transferring devices 180, 192, 194 are disposed adjacently to the metering station 196 to radially transfer slide elements 140, 144 which have been loaded into the outer ring 112. More particularly, the slide transferring devices 180, 192, and 194 are utilized to transfer non-potentiometric slide elements 144 (either rate chemistry or endpoint) to either the intermediate or inner slide element positions of the inner ring 108 or to the wash station 170. The remaining slide transferring device 180 is disposed on the opposite side of the metering station 196 adjacent to the read station 154. This specific transferring device 180 is preferably adjacent to the inner read station 150 and is used to shuttle colorimetric (e.g., rate) slide elements 144 to an inner eject slot 184 following a final read thereof in order to dispose of the slide elements which are no longer needed and further to create an empty slide element position 116 in the inner ring 108.

For purposes of this embodiment, three of the slide transferring devices 180, 192, 194 include a reciprocating pusher blade 200 having an independent drive mechanism. The pusher blade 200 has a length dimension which permits the end of the blade to engage an edge of a slide element 140, 144 and transfer the slide element into either one of the designated slide positions of the inner and outer rings 108, 112. The slide transferring device 188 also includes a reciprocating pusher blade 202 which is longer than the other pusher blades 200, this device being radially aligned with the entrance slot 176 of the wash station 174.

All of the sample elements, whether potentiometric 140 or colorimetric 144 in type, are initially loaded into the outer ring 112 using the slide transferring device 183, Figs. 10-12, located in the metering station 196. As intended herein by the present embodiment, the outer slide positions 122 provide an incubation area for potentiometric slide elements 140, as well as certain colorimetric slide elements 144, such as those requiring endpoint testing which requires only a single read be performed at the inner read station 150 following a predetermined incubation interval (e.g., approximately 5

minutes). Other colorimetric slide elements 144, such as those requiring rate chemistries, require a number of reads to be taken by the reflectometer and are preferably shuttled to the inner slide element positions by one of the pusher blade devices 192, 194 after the slide elements 144 have been loaded into the outer ring 112.

5 In a preferred method of operation and referring to Figs. 4-12, the incubator 100 of the present embodiment operates in the following manner.

 According to this particular embodiment, all spotted (metered) slide elements 140, 144 are initially loaded into the outer ring 112 of the rotor assembly 104 using the slide transferring device 183. Because the outer read station 160 is disposed in relation to the outer ring 112, potentiometric slide elements 140 are not transferred out of the outer ring 112 at any time. These slide elements 140 are therefore maintained in the outer ring 112 during the entire incubation process and are not shuttled to either of the interior slide positions 116, 118.

15 The gear drive mechanism drives the outer ring 112 incrementally, meaning that the outer ring is advanced one slide position per increment. The inner ring 108, on the other hand, is driven by drive belt 130 at an $N + 1$ increment in which N = one revolution of the ring, thereby incrementing the inner ring with respect to the outer ring 112 per predetermined movement thereof.

20 This provides a unique and highly efficient means for loading and advancing slides into and within the incubator. That is, the outer ring 112 can be incremented or indexed by one position at a predetermined interval (e.g. approximately 4.5 seconds). The independently driven inner ring 108 can be driven one full revolution plus one position ($N + 1$) over twice the predetermined time interval (approximately 9 seconds) of the outer ring 112. Each of the outer and inner rings 112, 108 can be synchronized at the stopping position. Therefore, the outer ring 112 will have advanced two positions while the inner ring will have advanced one position. For example, the above synchronization

When the inner ring 108 stops, up to two slide elements can then be loaded from the outer ring 112 into the inner ring 108 using blades 192, 194. According to a specific protocol, blade 194 will move a slide element from the outer slide element position 122 to a middle slide position 118 while blade 192 will move a slide element from the outer slide element position 122 to the innermost slide position 116. This using of tandem loading technique thereby maximizes the number of slides which can be processed by the incubator. It should be further apparent that the duration of the time intervals can be suitably varied.

In use and following a predetermined incubation interval, the potentiometric slide element 140 is tested at the outer read station 160 by the electrometer 163 in a conventionally known manner as the potentiometric slide element passes the outer read position 164. Following the read, the potentiometric slide element 140 is no longer required according to this embodiment. Therefore, the slide element 140 subsequently passes above an outer dump station 148, shown in Fig. 9, which is provided as a slotted portion of the circular track 138 adjacent the read station 160. As the outer ring 112 rotates in a counterclockwise direction according to the drawings, the slotted portion is exposed allowing the read slide element 140 to drop into the dump station 148.

On the other hand, all reflectometer reads are taken at the read station 150 which is located in alignment with the inner slide element positions 116 as they rotate over the reflectometer 153, Fig. 7. It is desired to get rate chemistry slide elements to the inner ring 108 as soon as possible using one of the slide element transferring devices 192, 194. The endpoint slide elements are shuttled using either of the slide element transferring devices 192, 194 to an intermediate slide element position 118 and subsequently to an inner slide element position 116 for reading and subsequent disposal through either eject slot 184 using the pusher blade 200 of the slide transferring device 180 or an adjacent eject slot 186, Fig. 8, disposed adjacently to the entrance slot 176 of

wash station 170 using pusher blade 202 of slide transferring device 188 following a reflectometer read at station 150, Fig. 4.

In the case of an immuno-wash requirement, a spotted colorimetric slide element 144 is initially loaded into the outer ring 112 at the metering station 196. As the outer ring 112 advances incrementally by means of the gear drive mechanism, the slide element 144 is engaged by the pusher blade 202 of slide
5 element transferring device 188 which pushes a slide element which is located in an inner slide element position 116 directly into the wash station 172 through the entrance slot 176 for immuno-rate wash. Preferably, the outer ring load stations 122 are raised in relation to those of the inner ring 108
10 permitting the pusher blade 202 to pass beneath a potentiometric element 140, as shown more closely in Fig. 8, without engaging therewith.

As previously noted and during wash, the slide element 144 is transferred to the wash station 170 through the entrance slot 176 by means of the pusher blade 202 to an input position. The slide element 144 is then
15 transferred by means of the pivotal shuttle 175 to a wash station and washed before the slide element is pivoted back to the input position and is reinserted back into the inner ring 108 through the slot 176 using the pusher blade 178. It should be noted that in order to perform this particular step, an empty inner slide element position 116 would have to be reserved in the inner ring 108 prior
20 to reinsertion of the washed slide element 144.

PARTS LIST FOR FIGS. 1-12

	10	incubator
	12	linear array
	13	row
	14	load stations
5	15	slot or receiving area
	16	row
	17	slot or receiving area
	18	slide element
	18A	slide element
10	18B	slide element
	19	openings
	20	first direction
	23	slide element transferring device
	25	slide element transferring device
15	30	read station
	31	slide supply
	32	metering station
	33	staging position
	34	second direction
20	38	dump station
	50	incubator assembly
	54	rotor assembly
	58	rotor assembly
	100	incubator
25	104	rotor assembly
	105	hot plate
	108	inner ring
	112	outer ring
	116	inner slide element position
30	118	intermediate slide element position
	122	outer slide element position
	126	cover
	130	drive belt
	134	V-bearings
35	138	track
	140	potentiometric slide element
	142	dump station
	144	colorimetric slide element
	148	slotted portion
40	150	inner read station
	153	reflectometer
	154	read location
	160	outer read station
	163	electrometer

	164	read position
	170	wash station
	172	wash position
	174	evaporator caps
	175	shuttle assembly
5	176	entrance slot
	177	holder for evaporator caps
	178	pusher blade
	179	evaporator caps
	180	slide transferring device
10	183	slide transferring device
	184	eject slot
	186	eject slot
	188	slide transferring device
	192	slide transferring device
15	194	slide transferring device
	196	metering station
	198	metering head
	200	reciprocating pusher blade
	202	reciprocating pusher blade
20	204	slide element supply
	206	bar code readers
	210	metering rail

Though the preceding has been described in terms of certain specific embodiments, it will be apparent that certain variations and modifications are possible which still embody the inventive concepts of the present invention. For example, any of the read stations can be otherwise disposed. For example, the reflectometer can be located in a read position which is fixedly held relative to the outer incubator ring. In this version, the electrometer can be located within the incubator; that is, radially inward of the inner ring. The potentiometric slide element 140 can be selectively picked from an outer slide element position 122 by means of a conventionally known picker assembly (not shown) and transferred to a read station (not shown) to then be read by the electrometer. The potentiometric slide element 140 following the read operation can then be shuttled by known means to an external dump station (not shown) for disposal thereof.

CLAIMS

1 1. An incubator for use in a clinical analyzer, said incubator
2 comprising:

3 an incubator housing;

4 at least one load station for accommodating at least one test sample;

5 a read station, said read station being disposed within said incubator
6 housing;

7 first drive means for driving at least one of test sample and said load
8 station in a first direction, said at least one load station having at least two
9 load positions arranged in a second direction, said second direction being
10 substantially orthogonal to said first direction; and

11 second drive means for selectively driving one of said at least one said
12 load station and said at least one test sample accommodated therein in said
13 second direction relative to said read station for reading said at least one test
14 sample.

1 2. An incubator as recited in Claim 1, including a ring assembly
2 having a plurality of circumferentially disposed load stations.

1 3. An incubator as recited in Claim 2, wherein said ring assembly
2 includes at least two concentric ring components, each of said ring components
3 being supported for rotation about a central axis of said incubator housing.

1 4. An incubator as recited in Claim 3, wherein said first drive
2 means includes means for driving said rotatably driving said ring assembly
3 about said central axis.

1 5. An incubator as recited in Claim 4, wherein said second drive
2 means includes means for selectively radially moving said at least one test
3 sample relative to said central axis from at least one load position.

1 6. An incubator as recited in Claim 5, wherein said second drive
2 means includes means for radially moving said at least one test sample
3 between at least a first load position and a second load position of a load
4 station.

1 7. An incubator as recited in Claim 6, wherein said read station is
2 disposed in relation to one of said ring components, such that said first drive
3 means can rotate one load position of each of said load stations into a read
4 position, said second drive means enabling at least one other load position of
5 at least one of said load stations to be selectively moved into the read position.

1 8. An incubator as recited in Claim 7, including a dump station
2 radially adjacent said read station.

1 9. An incubator as recited in Claim 1, wherein said read station
2 includes a device capable of detecting an optical property of a test sample.

1 10. An incubator as recited in Claim 9, wherein said device is a
2 reflectometer.

1 11. An incubator as recited in Claim 4, including third drive means
2 for selectively and radially removing at least one test sample from a load station
3 of said ring assembly for later reinsertion therein.

1 12. An incubator as recited in Claim 1, wherein said read station
2 includes a device capable of measuring an electrical property of a test sample.

1 13. An incubator as recited in Claim 12, wherein said device is an
2 electrometer.

1 14. An incubator as recited in Claim 1, including a plurality of slide

2 elements, each said slide element having a volume of a test sample metered
3 thereupon.

1 15. An incubator as recited in Claim 6, including shuttle means for
2 radially shuttling test samples into said incubator housing.

1 16. An incubator as recited in Claim 15, wherein said shuttle
2 means is circumferentially disposed immediately adjacent said second drive
3 means.

1 17. An incubator as recited in Claim 15, wherein said shuttle
2 means includes a reciprocating pusher blade disposed in relation to said
3 incubator housing to shuttle at least one test sample into at least one load
4 position of a load station.

1 18. An incubator as recited in Claim 15, wherein said shuttle
2 means is capable of shuttling at least two radially disposed test elements into
3 a load station simultaneously.

1 19. An incubator as recited in Claim 15, including a supply of
2 stacked slide elements, said shuttle means being disposed adjacent to slide
3 element supply.

1 20. An incubator as recited in Claim 3, wherein said first drive
2 means includes a belt drive wrapped about the periphery of at least one ring
3 component.

1 21. An incubator as recited in Claim 3, wherein said ring components
2 of said ring assembly are independently driven relative to one another by said
3 second drive means.

1 22. An incubator as recited in Claim 4, wherein at least two load
2 positions of a load station differ in height relative to one another.

1 23. An incubator for use in a clinical analyzer, said incubator
2 comprising:

3 an incubator ring assembly supported for rotation about an axle defining
4 an axis of rotation, said ring assembly including a plurality of circumferentially
5 defined load stations, each said load station having at least two load adjacent
6 radial load positions for receiving test samples;

7 at least one read station for reading at least one test sample at a read
8 position:

9 first drive means operatively connected to said incubator ring assembly
10 for rotating said ring assembly about said axis of rotation, said at least one said
11 read station being disposed such that a first plurality of circumferentially
12 disposed load positions can be selectively aligned with said read position; and

13 second drive means for radially moving a test sample from at least one
14 load position of a load station into the read position.

1 24. An incubator as recited in Claim 23, wherein said second drive
2 means includes shuttle means for shuttling at least one test sample into a load
3 station of said incubator ring assembly.

1 25. An incubator as recited in Claim 24, wherein said shuttle
2 means can selectively shuttle at least two radially adjacent test samples into
3 said incubator ring assembly simultaneously.

1 26. An incubator as recited in Claim 23, wherein at least one test
2 station includes a device capable of measuring an optical property of a test
3 sample.

1 27. An incubator as recited in Claim 26, wherein said device is a
2 reflectometer.

1 28. An incubator as recited in Claim 23, including means for
2 independently controlling the temperature and humidity of each test sample
3 loaded into said incubator ring assembly.

1 29. An incubator as recited in Claim 28, wherein said independent
2 temperature and humidity control means includes a slide cap disposed at each
3 load position.

1 30. An incubator as recited in Claim 23, wherein at least one test
2 station includes a device capable of measuring an electrical property of a test
3 sample.

1 31. An incubator as recited in Claim 30, wherein said device is an
2 electrometer.

1 32. An incubator as recited in Claim 23, including third drive means
2 for selectively removing at least one test sample from said incubator ring
3 assembly for subsequent reinsertion therein.

1 33. An incubator as recited in Claim 20, wherein said incubator ring
2 assembly includes at least two concentric rings, each of said concentric rings
3 being coupled to said first drive means.

1 34. An incubator as recited in Claim 27, wherein said reflectometer is
2 disposed in relation to the load positions of an inner ring of said incubator ring
3 assembly.

1 35. An incubator as recited in Claim 31, wherein said electrometer is
2 disposed in relation to the load positions of an outer ring of said incubator ring
3 assembly.

1 36. An incubator as recited in Claim 23, wherein adjacent radial load
2 positions of at least one load station differ in height relative to one another.

1 37. An incubator as recited in Claim 24, including a dump station
2 radially disposed in relation to said read station.

1 38. An incubator as recited in Claim 37, wherein said second drive
2 means transfer fresh test samples into empty load positions of said incubator
3 after test samples have been dumped.

1 39. A clinical analyzer comprising:
2 an analyzer housing; and
3 an incubator disposed within said analyzer housing, said incubator
4 including:

5 at least one load station for accommodating at least one test sample;
6 at least one read station;
7 first drive means for driving at least one of said at least one test sample
8 and said load station in a first direction, said at least one load station having
9 at least two load positions arranged in a second direction, said second direction
10 being substantially orthogonal to said first direction; and second drive means
11 for selectively driving at least one of said load positions and said at least one
12 test sample accommodated therein with respect to said read station for testing
13 said at least one test sample.

1 40. A clinical analyzer as recited in Claim 39, wherein said
2 incubator includes a ring assembly including at least two concentric rings,
3 each of said rings being supported for rotation about a primary axis, said first
4 drive means including means for rotating said incubator ring assembly and in
5 which each ring includes a plurality of circumferentially disposed load
6 positions.

1 41. A clinical analyzer as recited in Claim 40, wherein said second
2 drive means includes first shuttle means for radially shuttling at least one test
3 sample between radial load positions of said incubator ring assembly.

1 42. A clinical analyzer as recited in Claim 39, including a dump
2 station radially adjacent at least one read station.

1 43. A clinical analyzer as recited in Claim 41, wherein said first
2 shuttle means can selectively shuttle a test sample after said test sample has
3 been read at said read station.

1 44. A clinical analyzer as recited in Claim 41, including second
2 shuttle means for shuttling at least one test sample into a load station of said
3 incubator ring assembly.

1 45. A clinical analyzer as recited in Claim 44, wherein said second
2 shuttle means can selectively shuttle at least two test samples into a load
3 station of said incubator simultaneously.

1 46. A clinical analyzer as recited in Claim 44, including a slide
2 supply for supplying slide elements to said incubator, said slide supply being
3 operatively connected to said second shuttle means.

1 47. A clinical analyzer as recited in Claim 46, including metering
2 means for dispensing a volume of a test sample onto at least one slide element
3 prior to shuttling said slide element into said incubator.

1 48. A clinical analyzer as recited in Claim 47, wherein said metering
2 means is disposed in relation to said slide supply so as to meter a volume of
3 test sample onto a slide element to be shuttled by said second shuttle means
4 into a load position of a load station within said incubator.

1 49. A clinical analyzer as recited in Claim 40, including means for
2 selectively removing at least one test sample from said incubator, said clinical
3 analyzer further including wash means for washing said at least one selectively
4 removed test sample, said incubator further including means for loading said
5 at least one washed test sample back into said incubator ring assembly.

1 50. A clinical analyzer as recited in Claim 39, wherein said at least
2 one read station includes a device capable of measuring an optical property of
3 a test sample.

1 51. A clinical analyzer as recited in Claim 50, wherein said device is
2 a reflectometer.

1 52. A clinical analyzer as recited in Claim 39, wherein said at least
2 one read station includes a device capable of measuring an electrical property
3 of a test sample.

1 53. A clinical analyzer as recited in Claim 52, wherein said device is
2 an electrometer.

1 54. A method of incubating and reading test samples for a clinical
2 analyzer, said incubator comprising at least one load station for
3 accommodating at least one test sample and a read station disposed within an
4 incubator housing, the method comprising the steps of:

5 driving at least one of test sample and said load station in a first
6 direction, said at least one load station having at least two load positions
7 arranged in a second direction, said second direction being substantially
8 orthogonal to said first direction; and

9 selectively driving at least one said load station and said at least one test
10 sample accommodated therein in the second direction to locate at least one test
11 sample relative to said read station for testing said at least one test sample.

1 55. A method as recited in Claim 54, in which said incubator
2 includes a ring assembly, said ring assembly including at least two concentric
3 ring components defining a plurality of circumferentially disposed load stations
4 wherein the first driving step includes the step of rotating said ring assembly
5 about a central axis.

1 56. A method as recited in Claim 55, including the steps of:
2 reading a first test sample which has been rotated into alignment with said
3 read station;

4 radially driving an adjacent second test sample into alignment
5 with said read station; and

6 reading said second test sample.

1 57. A method as recited in Claim 56, including the step of dumping
2 each of said test samples from said ring assembly after said reading steps.

1 58. A method as recited in Claim 57, including the step of loading
2 new test samples into said load station after said dumping step.

1 59. A method as recited in Claim 58, wherein said loading step
2 includes the step of simultaneously radially shuttling at least two test samples
3 into said load station.

ABSTRACT

An incubator includes an incubator ring assembly having at least two concentric rings supported for rotation about a common axle defining an axis of rotation. Each concentric ring includes a plurality of circumferentially defined load positions, each load position being sized for accommodating a test sample. At least one test station is arranged in relation to the plurality of load positions to selectively test a test sample, the test samples being are sequentially shuttled into and out of load positions of at least one of the concentric rings to increase the overall throughput of the analyzer.

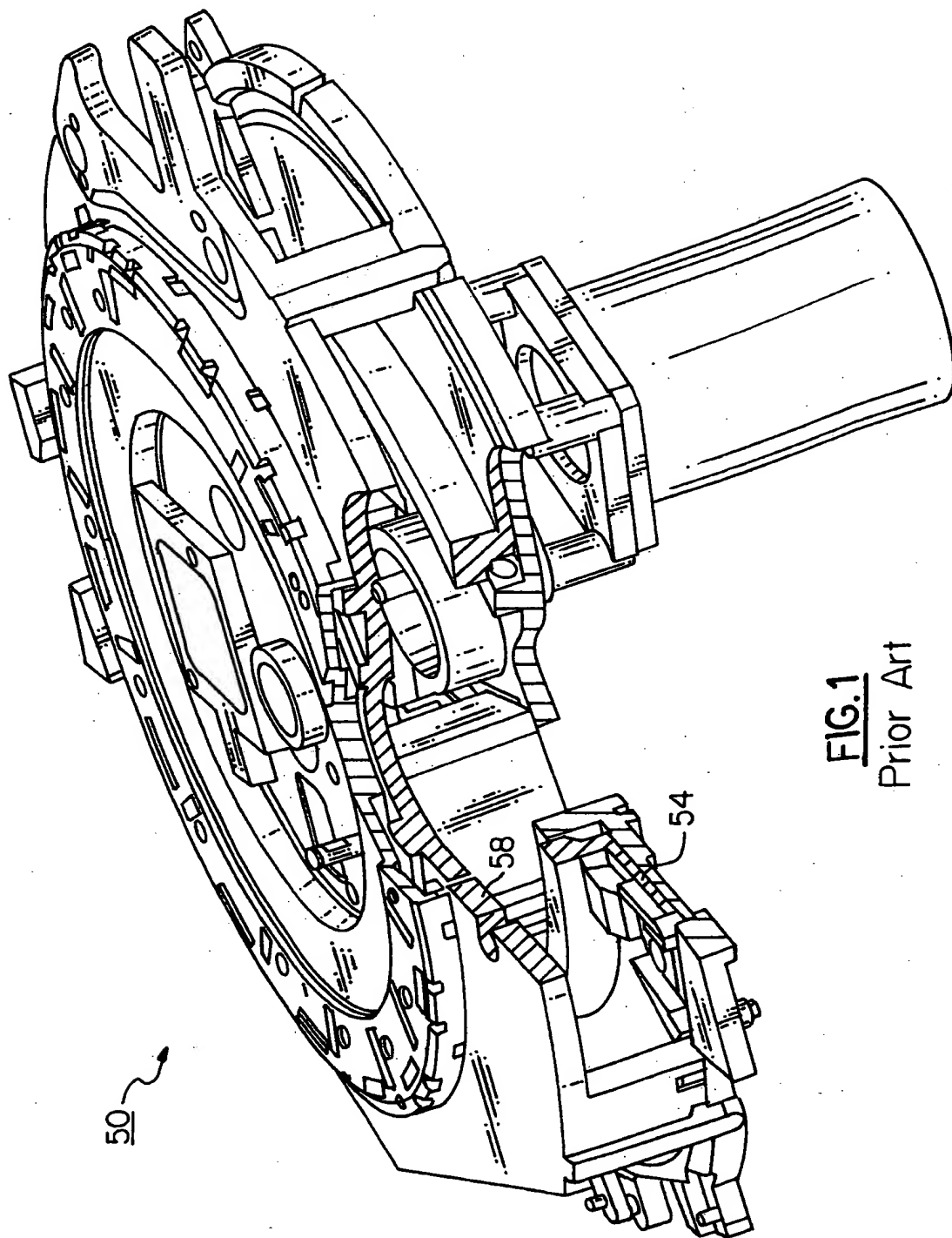


FIG. 1
Prior Art

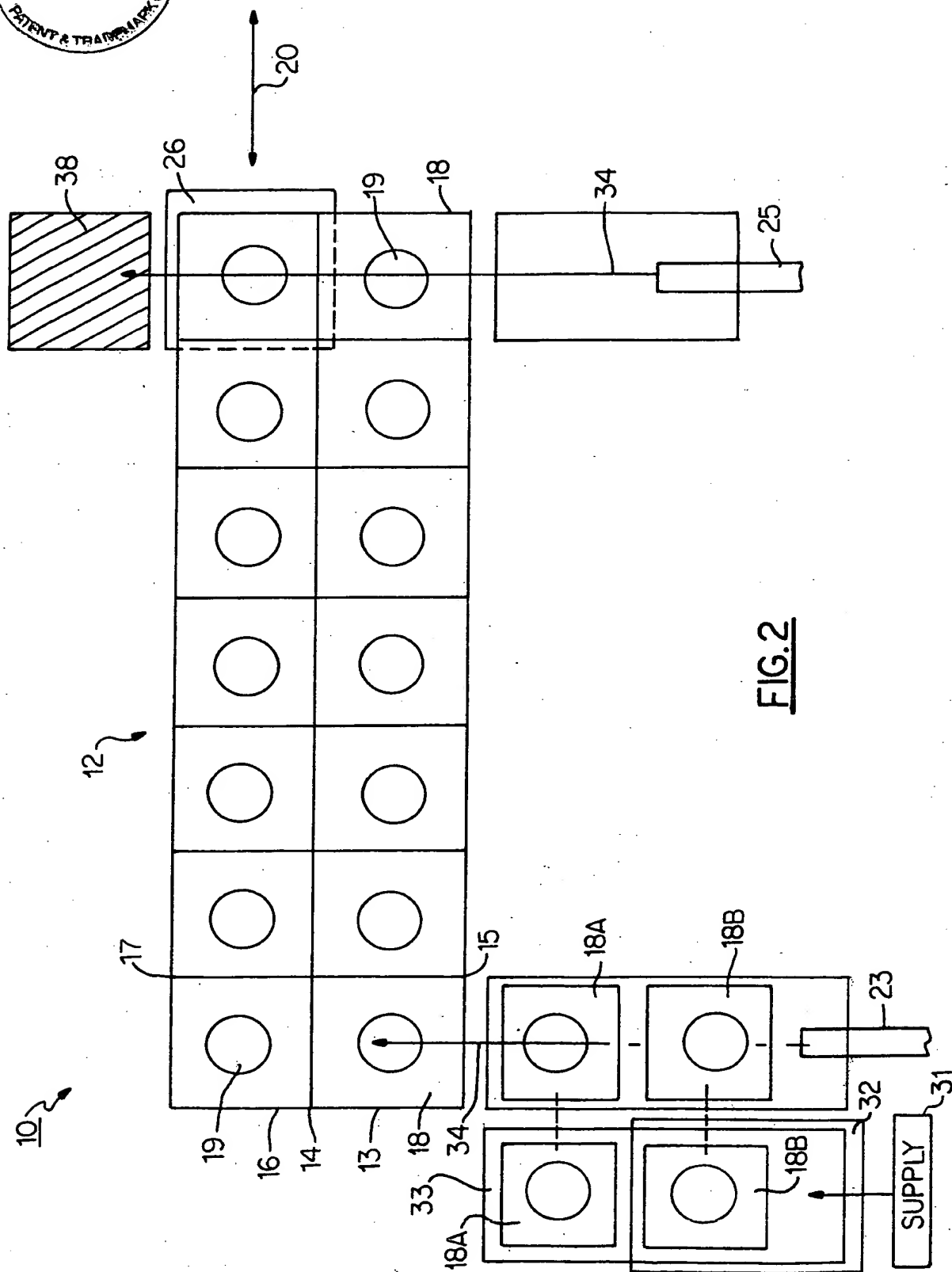


FIG.2

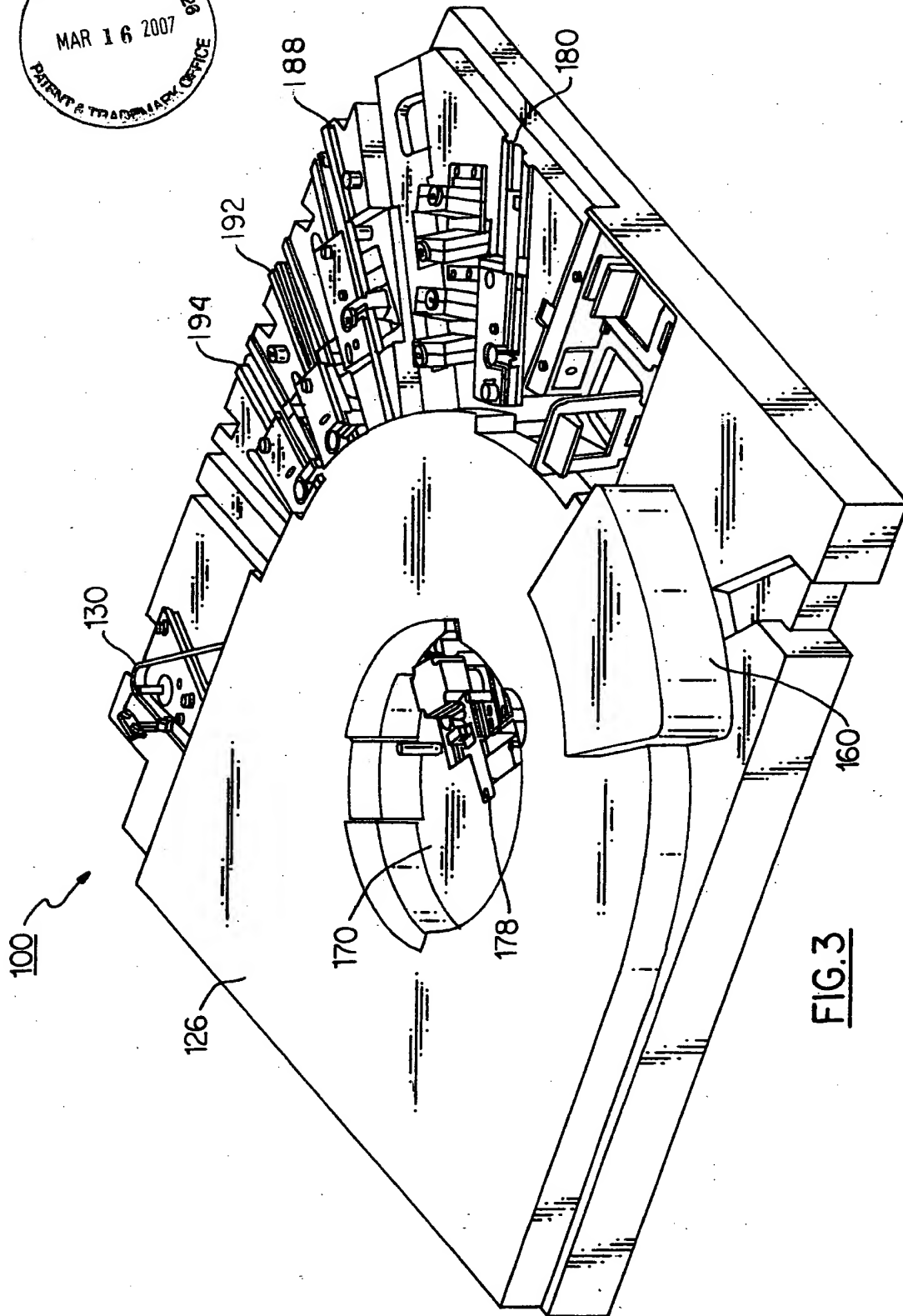
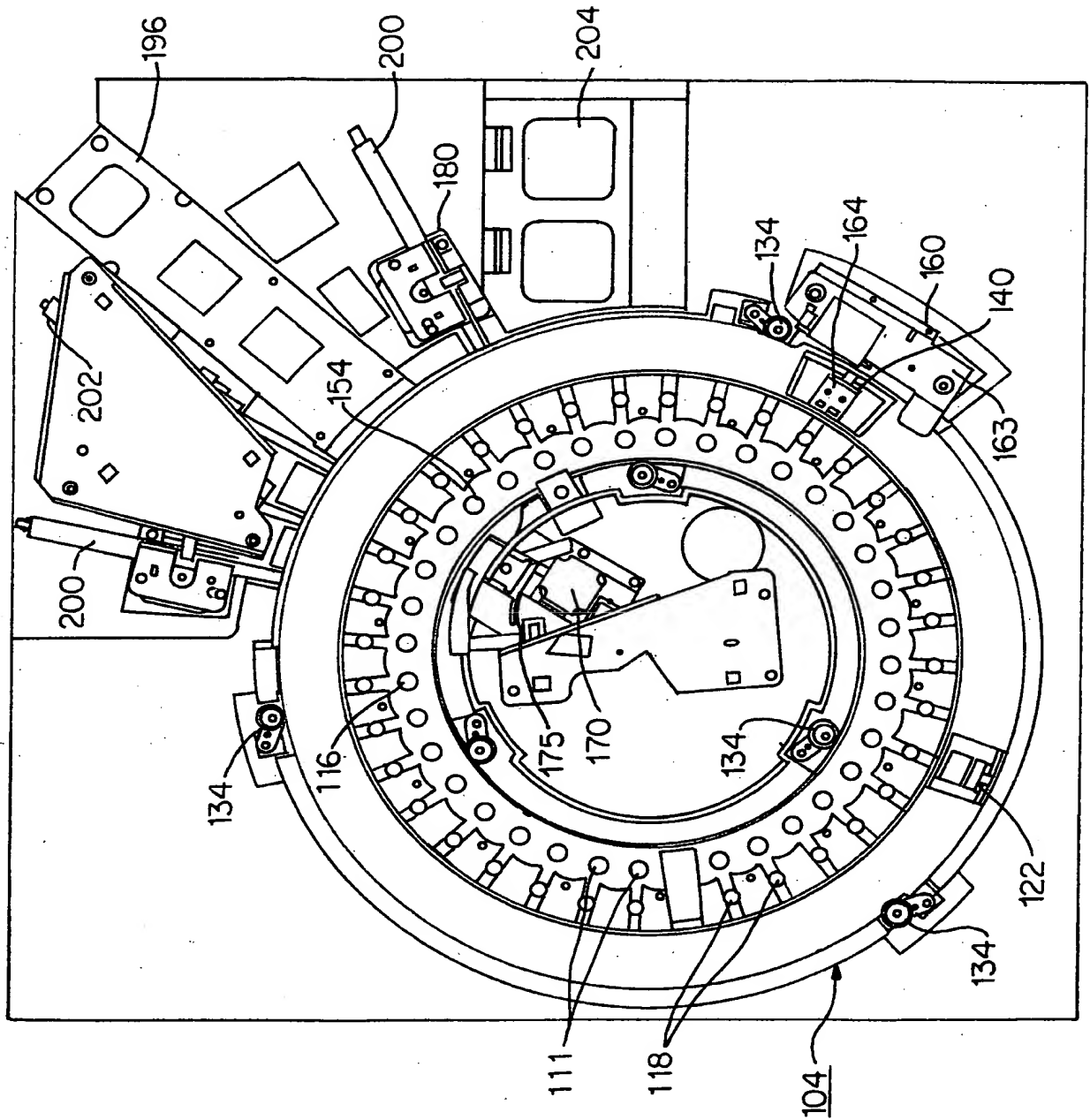


FIG. 3



FIG.4



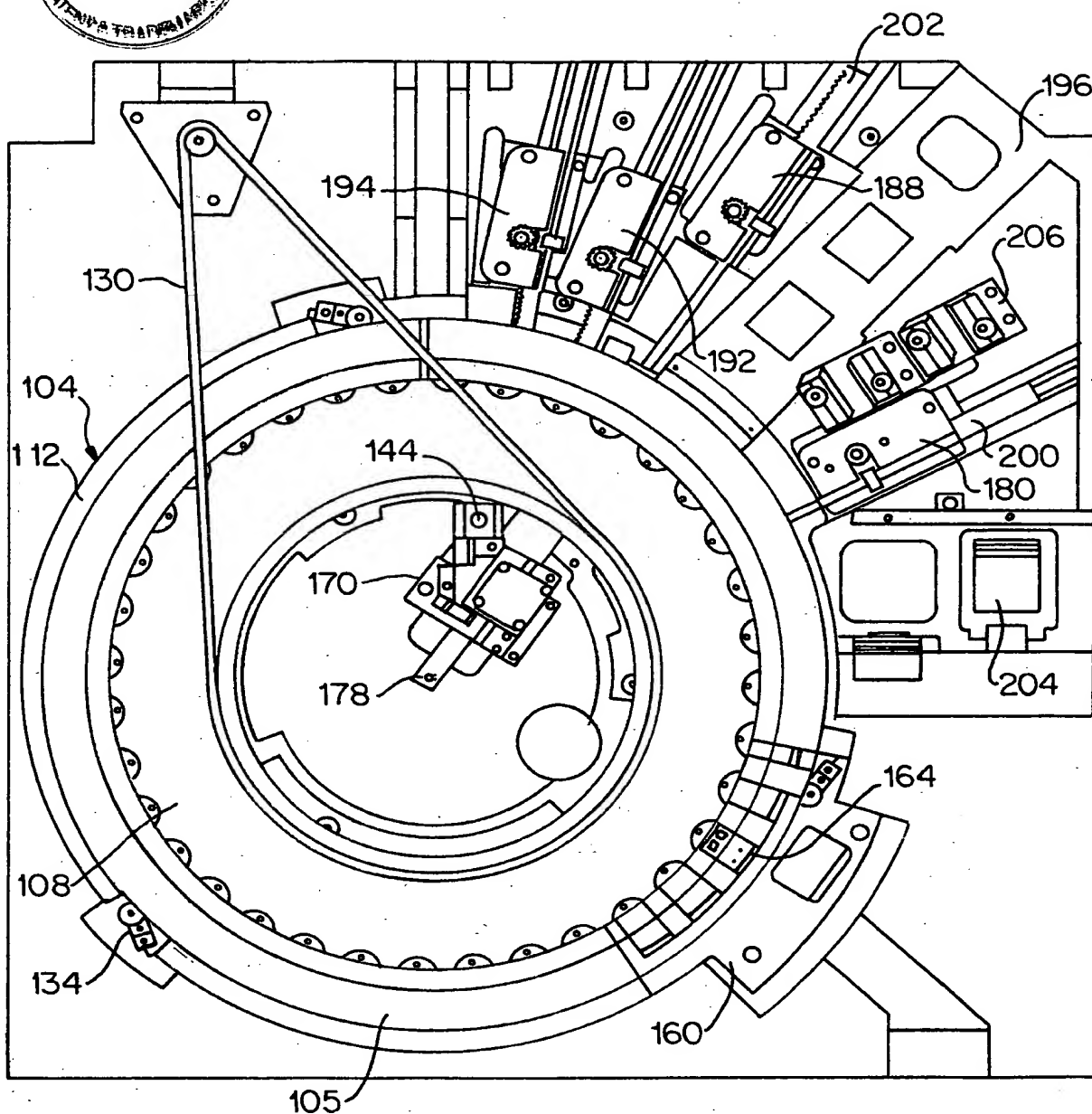


FIG. 5

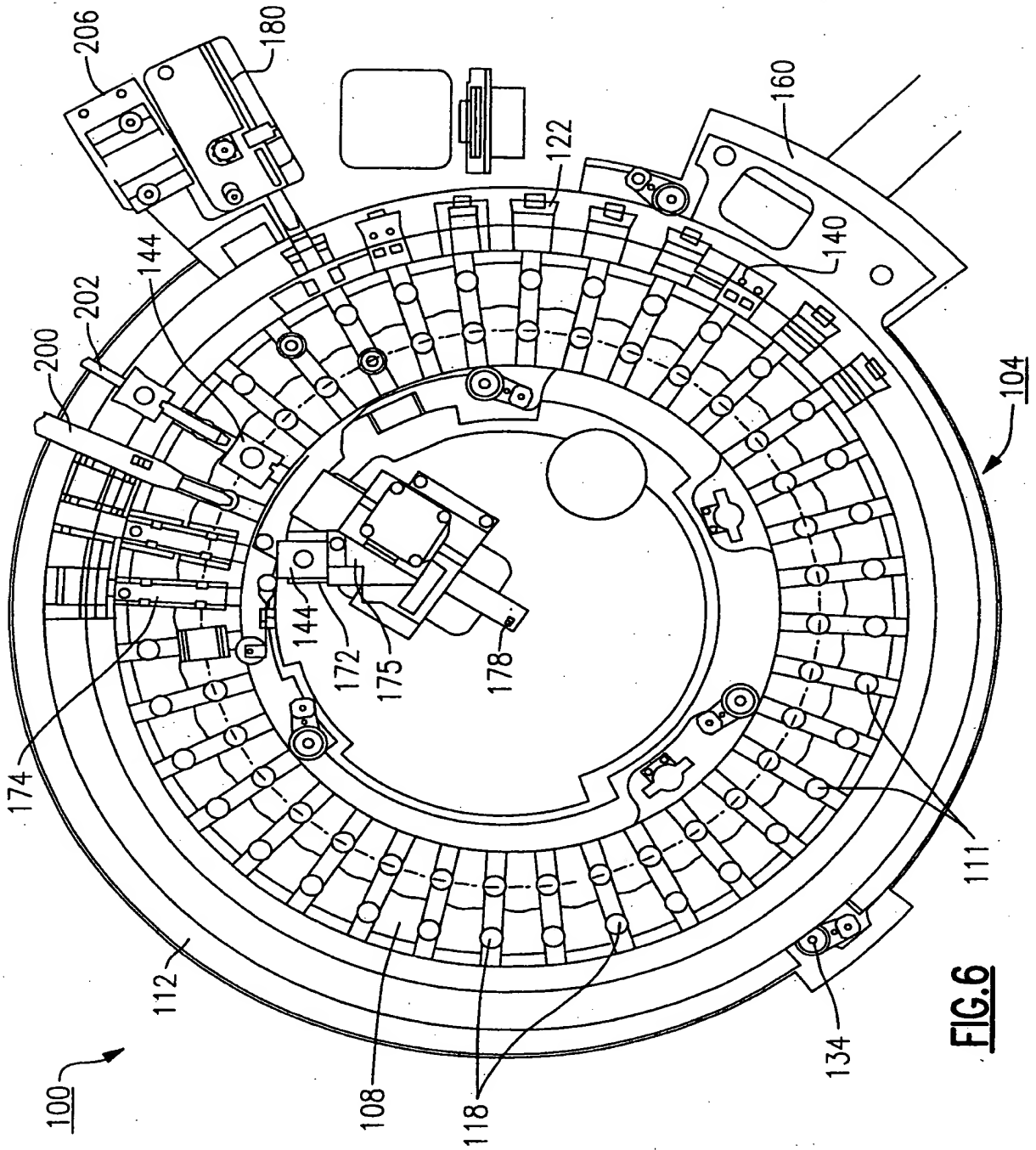


FIG. 6

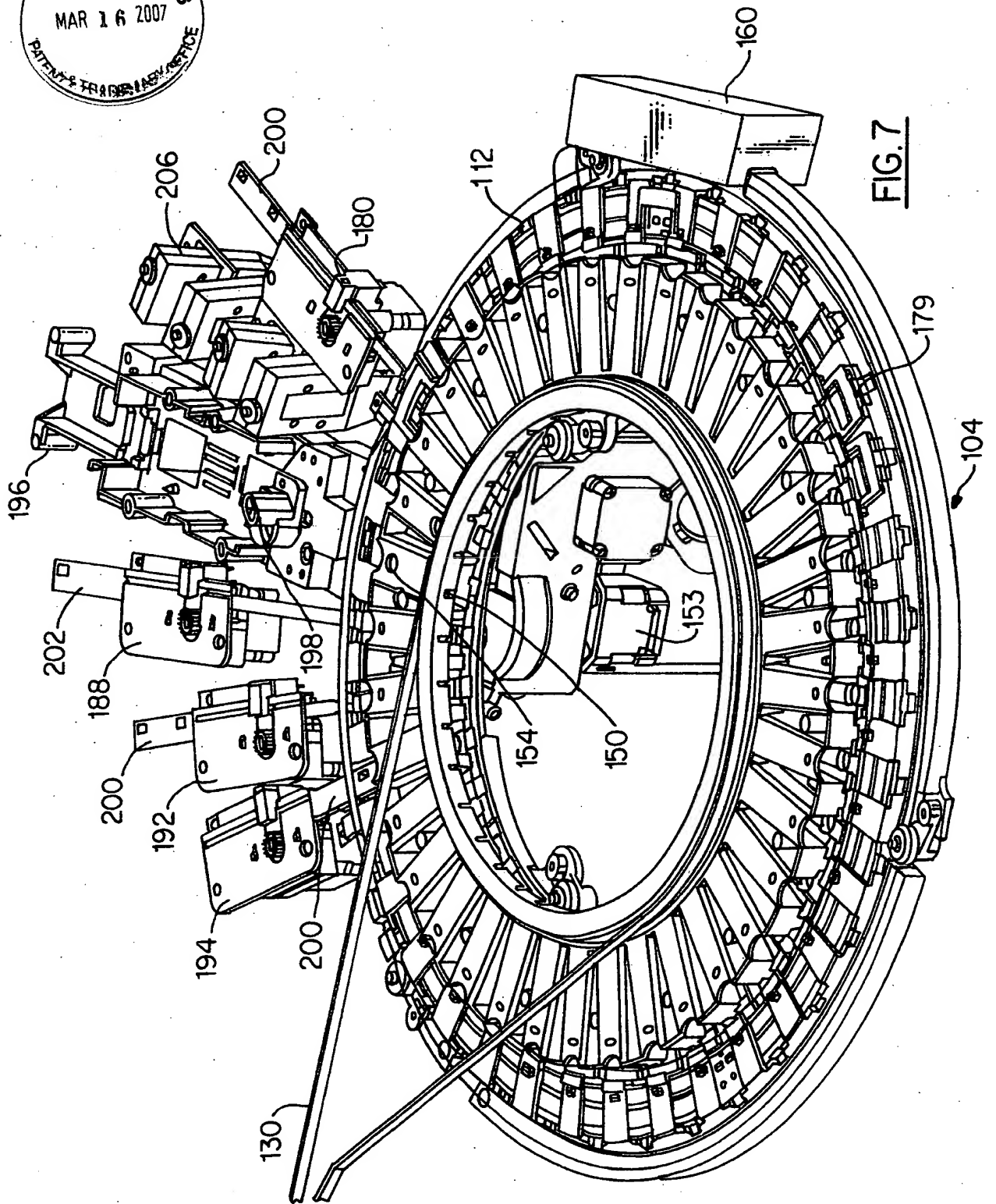


FIG. 7

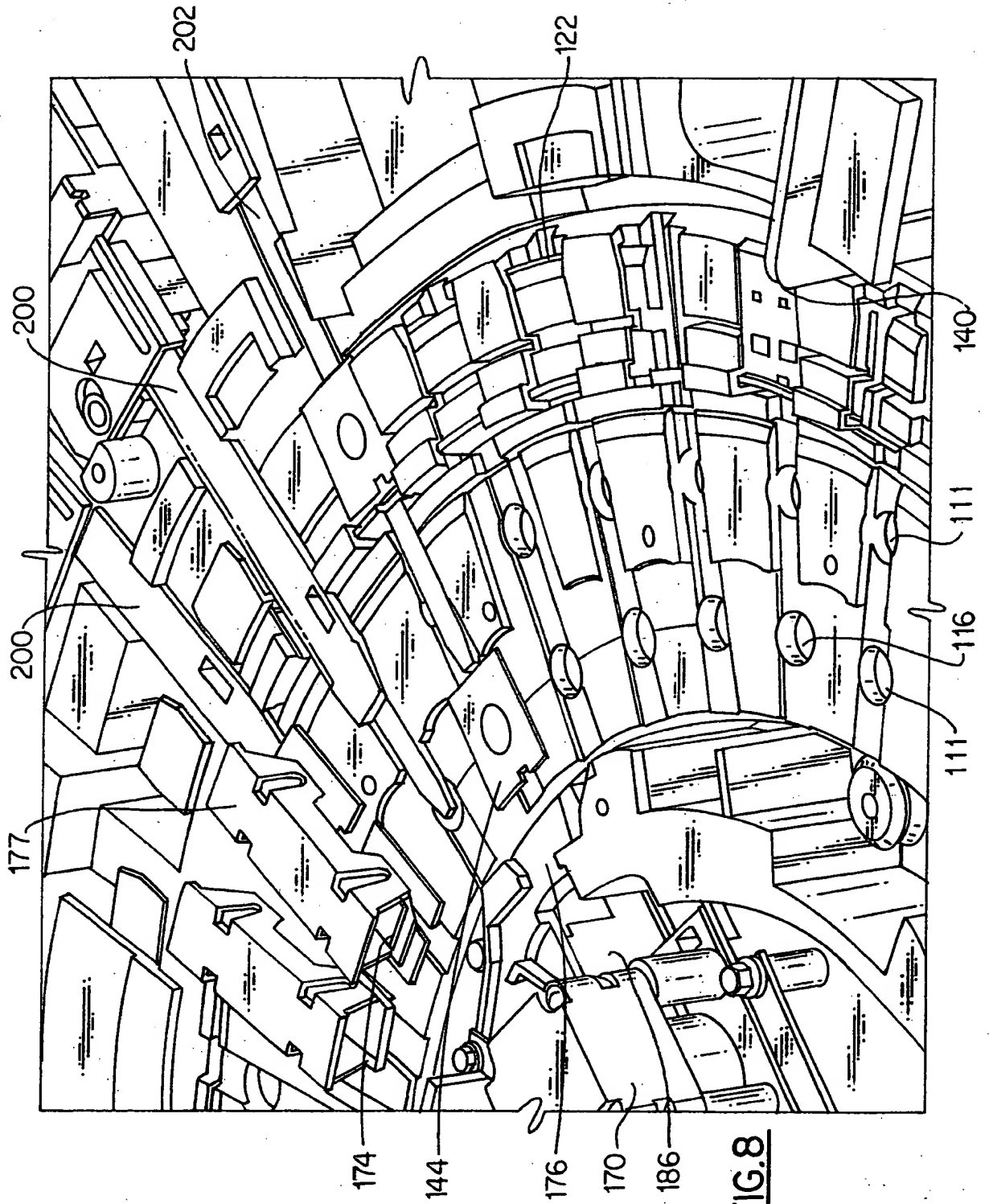


FIG. 8

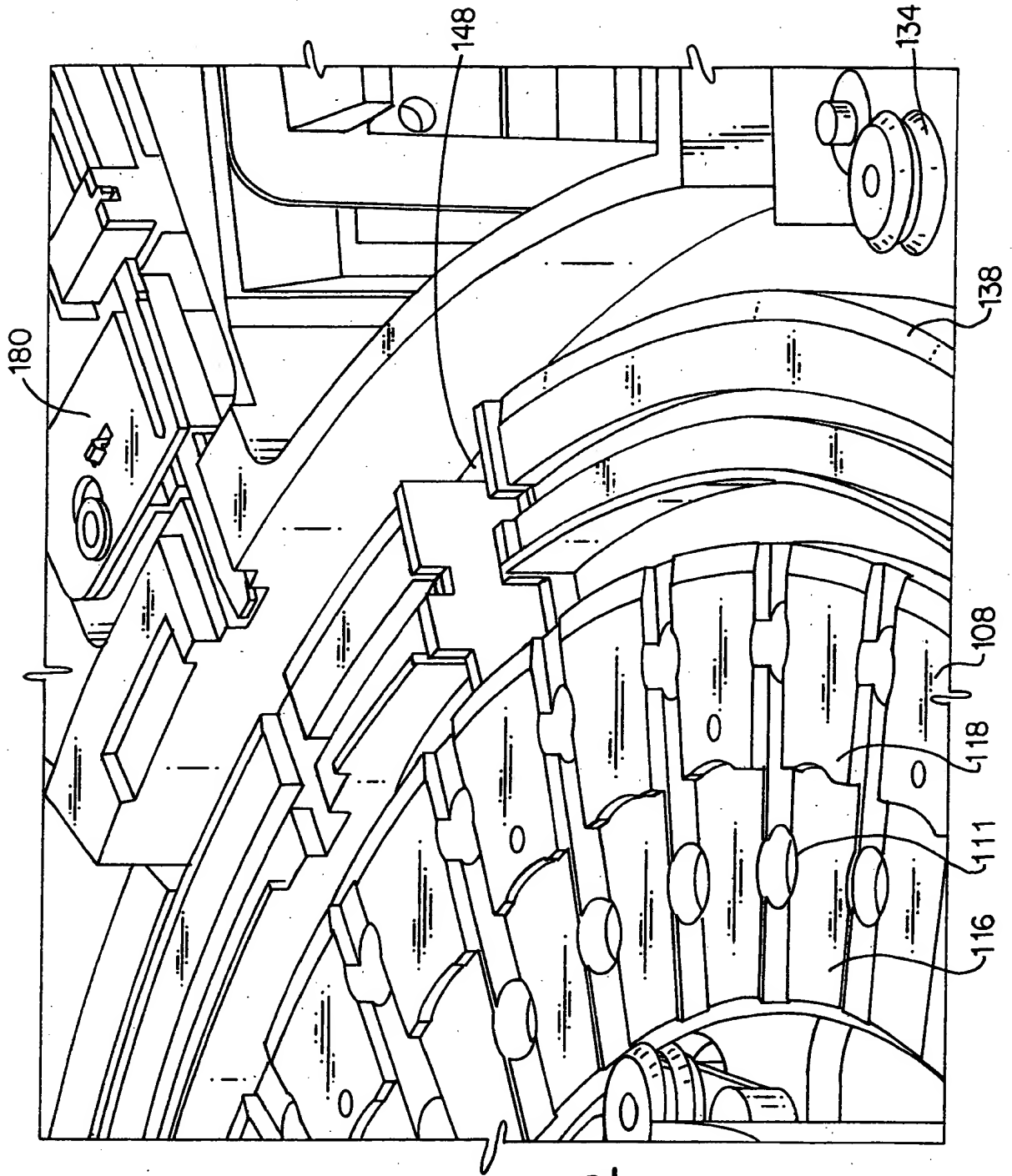


FIG. 9

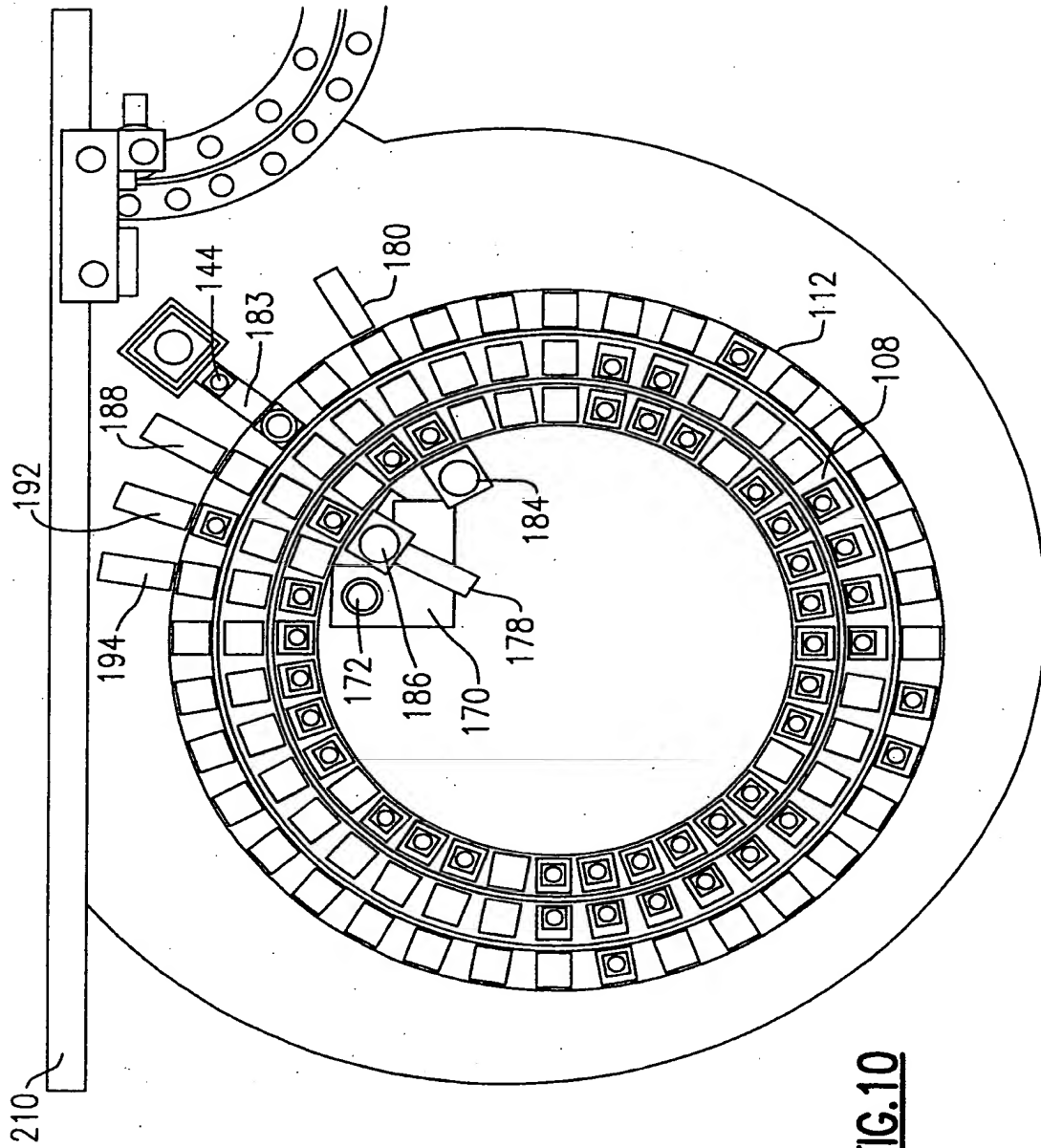


FIG.10

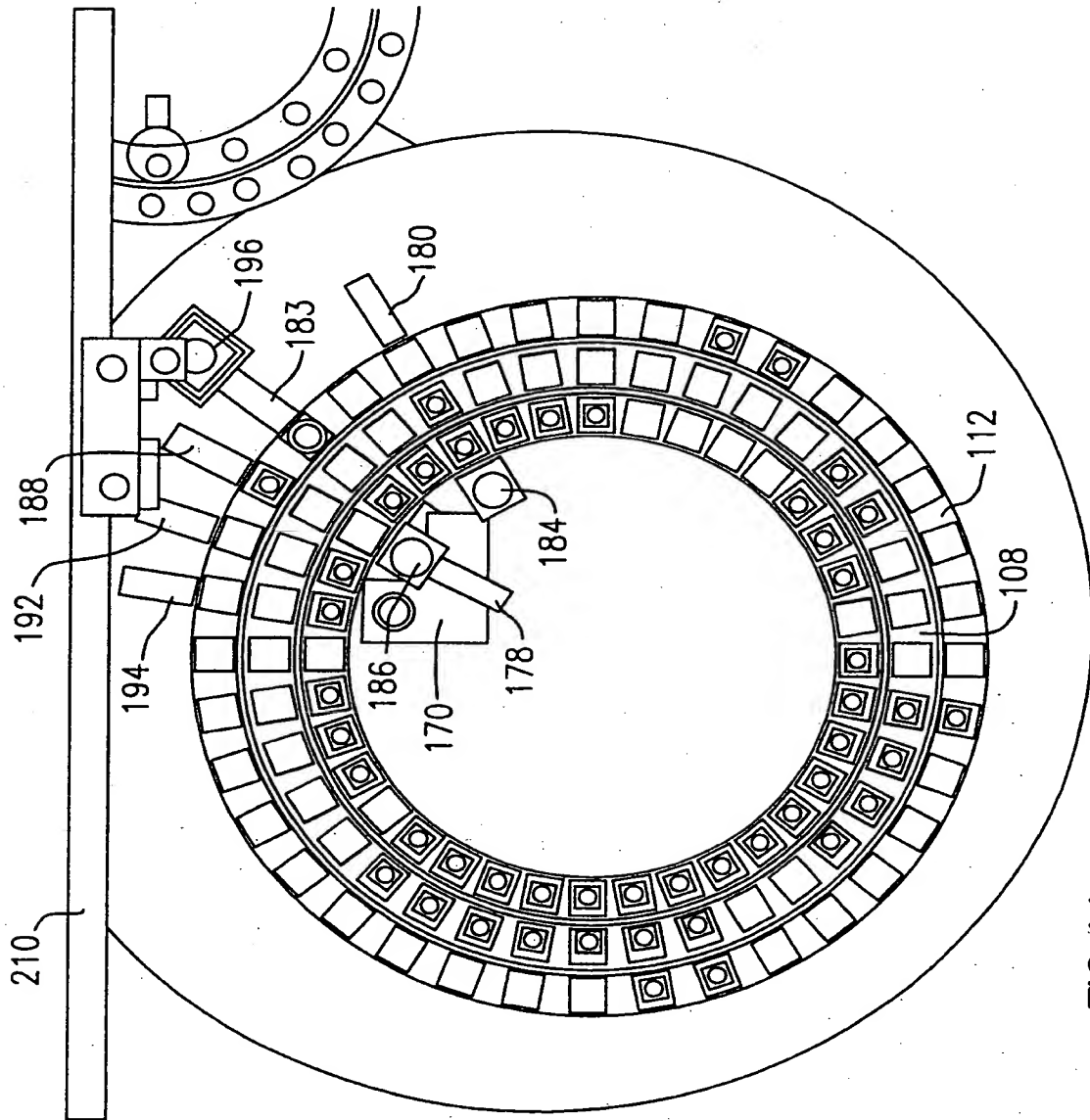


FIG.11

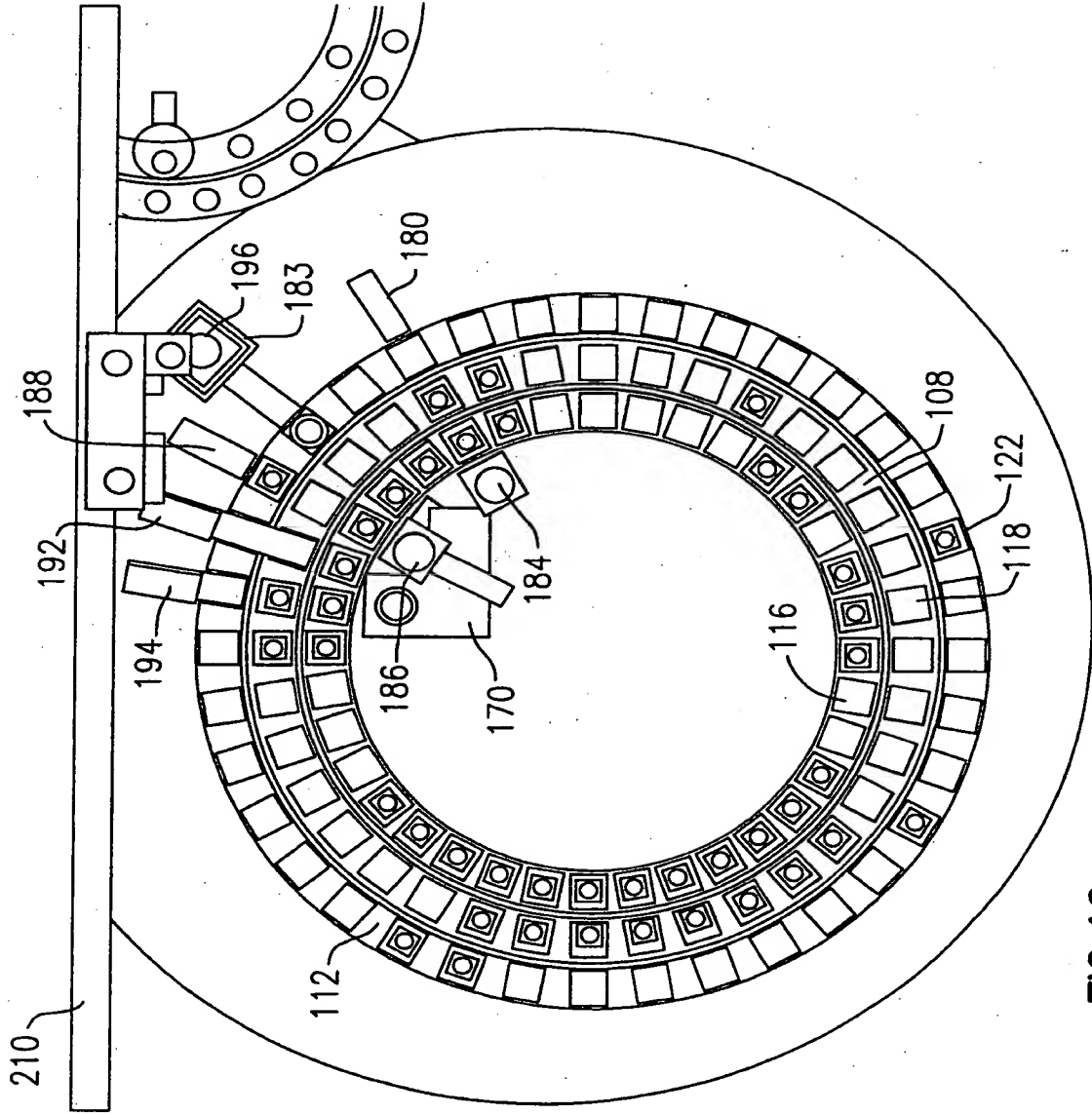
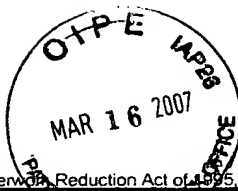


FIG.12

B



PTO/SB/21 (09-04)

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/904,692
Filing Date	July 13, 2001
First Named Inventor	Raymond Francis Jakubowicz
Art Unit	1743
Examiner Name	Lyle Alexander
Attorney Docket Number	961_002RCE

Total Number of Pages in This Submission	19
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ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return Mailroom Postcard; and Certificate of Express Mailing.
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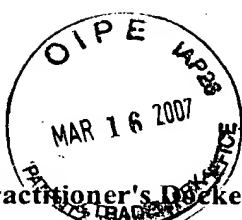
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Firm or Individual name	Wall Marjama & Bilinski LLP	Reg. No. 35,067
Signature		
Date	July 11, 2006	

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Practitioner's Docket No.: 961_002RCE

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Raymond Francis Jakubowicz et al.

Serial No.: 09/904,692

Art Unit: 1743

Filed: July 13, 2001

Examiner: Lyle Alexander

Confirmation No.: 4749

For: TANDEM INCUBATOR FOR CLINICAL ANALYZER

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Susanne C. Pelose
Susanne C. Pelose

AMENDMENT

Sir:

In response to the non-final Office Action, dated April 14, 2006, please amend the above-captioned patent application, without prejudice, as follows:

Amendments to the Claims are provided with the listing of claims beginning on page 2 of this paper.

Remarks begin on page 10 of this paper.

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the above-captioned patent application:

Listing of Claims:

1. (Canceled).
2. (Canceled).
3. (Currently Amended) An incubator as recited in Claim 62, wherein each of said inner and outer rings are supported for rotation by said at least one first drive mechanism about a central axis of an incubator housing.
4. (Canceled).
5. (Canceled).
6. (Currently Amended) An incubator as recited in Claim 3, wherein at least one of said first and second pluralities of circumferentially disposed slide element receiving areas includes at least two radially adjacent slide element receiving stations ~~disposed in said areas~~ wherein said at least one reciprocating pusher blade assembly of one of said second drive mechanisms ~~is capable of~~ can selectively radially ~~moving~~ move said at least one slide element between at least said at least two adjacent slide element receiving areas.
7. (Currently Amended) An incubator as recited in Claim 6, including at least one read station disposed in relation to one of said inner and outer rings, such that said at least one first drive mechanism can rotate one slide element receiving area into a read position, said at least one reciprocating pusher blade assembly enabling a slide element to be selectively and radially moved from a radially adjacent slide element receiving area into the read position.

8. (Original) An incubator as recited in Claim 7, including a dump station radially adjacent said read station.

9. (Previously Presented) An incubator as recited in Claim 7, wherein said read station includes a device capable of detecting an optical property of a test slide element.

10. (Original) An incubator as recited in Claim 9, wherein said device is a reflectometer.

11. (Currently Amended) An incubator as recited in Claim 62, wherein said at least one reciprocating pusher blade assembly of said at least two second drive mechanisms can selectively and radially ~~removes~~ remove at least one slide element from said incubator for later reinsertion therein.

12. (Previously Presented) An incubator as recited in Claim 7, wherein said read station includes a device capable of measuring an electrical property of a slide element.

13. (Original) An incubator as recited in Claim 12, wherein said device is an electrometer.

14. (Previously Presented) An incubator as recited in Claim 62, including a plurality of dry slide elements, each of said dry slide elements having a volume of a patient sample fluid metered thereupon prior to entry into said incubator.

15. (Currently Amended) An incubator as recited in Claim 6, wherein ~~said~~ at least one reciprocating pusher blade assembly of said at least two second drive mechanisms radially shuttles slide elements into and out of said incubator housing.

16. (Currently Amended) An incubator as recited in Claim 15, wherein ~~said at least one reciprocating pusher blade assembly is~~ at least two of said at least two second drive mechanisms are circumferentially disposed immediately adjacent in relation to at least one of said ~~first~~ inner ring and said ~~second~~ outer ring.

17. (Currently Amended) An incubator as recited in Claim 15, wherein said at least one reciprocating pusher blade assembly of each of said at least two second drive mechanisms is disposed in relation to said incubator ~~housing~~ to shuttle at least one slide element into at least one slide element receiving station.

18. (Currently Amended) An incubator as recited in Claim 15, wherein said at least one reciprocating pusher blade assembly of each of said two second drive mechanisms is capable of shuttling can move at least two radially disposed slide elements into radially adjacent slide element receiving areas or receiving stations simultaneously.

19. (Currently Amended) An incubator as recited in Claim 15, including a supply of stacked slide elements, at least one said ~~reciprocating pusher blade assembly~~ second drive mechanism being disposed adjacent to said slide element supply.

20. (Currently Amended) An incubator as recited in Claim 62, wherein said at least one first drive mechanism includes a drive belt ~~drive~~ wrapped about the periphery of at least one of said inner and outer rings.

21. (Previously Presented) An incubator as recited in Claim 62, wherein said inner and outer rings are independently driven relative to one another by said at least one first drive mechanism.

22. (Previously Presented) An incubator as recited in Claim 62, wherein at least two load positions of a slide element receiving area differ in height relative to one another.

- 23. (Canceled).
- 24. (Canceled).
- 25. (Canceled).
- 26. (Canceled).
- 27. (Canceled).
- 28. (Canceled).
- 29. (Canceled).
- 30. (Canceled).
- 31. (Canceled).
- 32. (Canceled).
- 33. (Canceled).
- 34. (Canceled).
- 35. (Canceled).
- 36. (Canceled).
- 37. (Canceled).
- 38. (Canceled).
- 39. (Canceled).
- 40. (Canceled).
- 41. (Canceled).
- 42. (Canceled).
- 43. (Canceled).
- 44. (Canceled).
- 45. (Canceled).
- 46. (Canceled).
- 47. (Canceled).
- 48. (Canceled).

49. (Canceled).

50. (Canceled).

51. (Canceled).

52. (Canceled).

53. (Canceled).

54. (Canceled).

55. (Canceled).

56. (Currently Amended) A method as recited in Claim 63, including the additional steps of:

reading a first slide element which has been rotated into alignment with a read station;

radially driving an adjacent second slide element into alignment with said read station using at least one of said reciprocating pusher blade assemblies; and

reading said second slide element.

57. (Previously Presented) A method as recited in Claim 56, including the step of dumping each of said slide elements from said inner ring after said reading steps.

58. (Currently Amended) A method as recited in Claim 57, including the step of radially loading at least one slide element from the outer ring into said inner ring using at least one reciprocating pusher blade assembly after said dumping step.

59. (Previously Presented) A method as recited in Claim 58, wherein said loading step includes the step of simultaneously radially shuttling at least two adjacent test slide elements into radially adjacent slide element receiving areas.

60. (Canceled).

61. (Canceled).

62. (Currently Amended) A sequential tandem incubator for use in a clinical analyzer, said incubator comprising:

an inner ring and an outer ring, said outer ring including a first plurality of circumferentially disposed slide element receiving areas and said inner ring including a second plurality of circumferentially disposed slide element receiving areas, each of said first and second pluralities of slide element receiving areas being radially adjacent to one another on a common horizontal plane;

at least one first drive mechanism for driving at least one of said inner and outer rings rotationally about at least one axis and within said common horizontal plane; and

at least ~~one~~ two second drive ~~mechanism~~ mechanisms for selectively moving slide elements ~~exclusively~~ in a radial direction exclusively within ~~along~~ said common horizontal plane into and out of said incubator and between said first and second plurality of said circumferentially disposed slide element receiving areas in order to increase throughput of said incubator, each of said at least ~~one~~ two second drive ~~mechanism~~ mechanisms including at least one reciprocating pusher blade assembly for loading slide elements into one of said inner ring and said outer ring and for moving slide elements between said inner ring and said outer ring.

63. (Currently Amended) A method of incubating and reading test slide elements using a sequential random incubator in a clinical analyzer, said sequential random incubator comprising an inner ring and an outer ring, said outer ring including a first plurality of circumferentially disposed slide element receiving areas and said inner ring including a second plurality of circumferentially disposed slide element receiving areas, each of said first and second pluralities of slide element receiving areas being radially adjacent to one another within ~~on~~ a common horizontal plane, said method comprising the steps of:

radially loading at least one slide element into an empty slide element receiving area ~~using a reciprocating pusher blade assembly disposed in relation to one of said inner ring and said outer ring;~~

rotating at least one of said inner and outer rings within along the common horizontal plane; and

moving said at least one slide element radially between said first and second pluralities of radially adjacent slide element receiving areas of said incubator ~~along within~~ said common horizontal plane so as to improve the throughput of said incubator, wherein said radially loading and said radially moving ~~step is~~ steps are performed using at least two ~~one~~ reciprocating pusher blade ~~assembly~~ assemblies disposed in relation to said ~~inner ring and said outer ring~~ incubator and within said common horizontal plane.

64. (Currently Amended) An incubator as recited in Claim ~~[[17]]~~ 62, wherein a plurality of second drive mechanisms ~~reciprocating pusher blade assemblies~~ are disposed at predetermined circumferential locations adjacent to said inner and outer rings, each of said second drive mechanisms including a reciprocating pusher blade assembly.

65. (Currently Amended) An incubator as recited in Claim ~~[[64]]~~ 62, wherein at least one reciprocating pusher blade assembly is radially disposed on the interior of said inner ring.

66. (Currently Amended) An incubator as recited in Claim 64, wherein each of said plurality of second drive mechanisms ~~reciprocating pusher blade assemblies~~ are circumferentially disposed at predetermined locations about said outer ring, wherein the reciprocating pusher blade assemblies of at least two of said plurality of second drive mechanisms can load and unload at least one slide element in relation to said incubator and can further radially move at least one slide element between slide element receiving areas as the inner ring and outer ring are rotated by

Serial No.: 09/904,692
Amendment Dated: July 11, 2006
Reply to Office Action of April 14, 2006

the first drive mechanism in order to move each of said first and second pluralities of slide elements receiving areas being movable into registration with said second drive mechanism ~~capable of moving radially through each of said inner and outer rings.~~

- 67. (Canceled).
- 68. (Canceled).
- 69. (Canceled).
- 70. (Canceled).
- 71. (Canceled).

REMARKS

The above-captioned patent application has been carefully reviewed in light of the non-final Office Action to which this Amendment is directed. Claims 3, 6, 7, 11, 15-20, 56, 58, and 62-66 have been further amended in an effort to further clarify and distinctly describe that which is regarded as the present invention. Claim 67 has been canceled. To that end, it is believed no new matter has been added.

Claims 3, 6-22, 56-59, and 62-67 are pending. The Examiner has rejected all of the above pending claims on the basis of certain prior art. More specifically, the Examiner has rejected all of the pending claims under 35 USC §102(b) as being unpatentable over Jakubowicz (U.S. Patent No. 5,244,633) and Claims 3, 6-22, 56-59, and 62-71 as being unpatentable over Miller, Muszak et al. or Carey et al. in view of Hamilton under 35 USC §103(a). Applicant herein respectfully requests reconsideration based on the amended claims, as well as the following discussion.

Turning first to the prior art rejection based on Jakubowicz '633, and in order to anticipate under the Statute, each and every claimed limitation must be found or its substantial equivalent in the single cited reference. Those limitations that are not found must be notoriously well known to one of ordinary skill in the field of the invention at the time thereof.

Jakubowicz '633 relates to an incubator that includes a pair of rotors or rings, each of the rotors having a number of receiving areas there within. As noted in previous correspondence, the instant '633 reference does not utilize slide elements, but rather utilizes a series of cup-like reaction vessels or cuvettes that are placed in each of the plurality of receiving areas. These cuvettes appear to be initially loaded into the outer ring by some form of device (which is neither shown nor described in this reference) that vertically loads the cuvettes by dropping or otherwise placing them into an appropriate receiving area. Therefore, the cuvettes are not radially loaded into the incubator nor is any device shown or suggested that is capable of such a function.

Another significant difference noted in previous correspondence by Applicant is that Jakubowicz '633 does not utilize a reciprocating pusher blade assembly to effect loading and movement of elements into or through the ring structure of their incubator. It is further submitted that a reciprocating pusher blade assembly would not be functionally effective in order to move the cuvettes that are illustrated by this primary reference. As is readily apparent from this reference, the cuvettes cannot simply be supported at their bottom ends due to their cup-shaped design, as opposed to the relatively flat planar support design that comprises slide elements.

Referring back to the cited reference, the push/pull rod mechanism, see Fig. 14 of Jakubowicz '633, that is used to move the cuvettes between the outer ring and the inner ring is described at col. 6, line 59 – col. 7, line 27, and is referred to as a transfer means 200 comprising a push rod 202, 204. As described therein, each of the rods are used for a specific aspect of transfer wherein rod 202 is used to effectuate transfer between the outer ring and the inner ring and the remaining rod 204 is used to effectuate transfer from the inner ring to a dump station (not shown). Each rod 202, 204 includes a terminal lip 206 that is disposed sufficiently to engage the interior of a cuvette at the top of the cuvette and wherein each rod is pulled toward axis 55. See Figs. 14-16. As such, a two part operation is necessary to effectuate transfer using each of the two rods and in which support is required at the top of the cuvette in order to effectively transfer the cuvette between the rings of the incubator.

Reciprocating pusher blade assemblies are specifically designed to support slide elements because these latter elements do not have a high aspect ratio in terms of height/width (diameter). The cuvettes of Jakubowicz, however, could not be maintained successfully for movement using a pusher blade without tipping of the cuvette and its contents. If a pusher blade assembly were utilized in order to effectuate movement of the cuvettes of Jakubowicz '633, there would be no stability afforded for the upper portions of the cuvettes and as such these elements could tip and spill their liquid contents. As a result, it is believed such support would not be

desired, mandating the use of the rod mechanism as described by Jakubowicz or a similar structure in order to support the upper portions of the cuvette and prevent tipping. Therefore, it is believed that neither the cuvettes nor the push/pull rod mechanism are suitable structural equivalents to the slide elements and the reciprocating pusher blade assemblies presently recited by Claims 62 and 63 of the present invention and that a person of ordinary skill in the field would not be motivated to make such substitutions.

Moreover, the present apparatus and method employs at least two reciprocating pusher blade assemblies, each of which is capable of moving a slide element not only between the rings of the incubator, but also for movement into and out of the incubator wherein each of these movements is accomplished within a common horizontal plane. As previously noted, Jakubowicz '633 fails to teach any means of loading their cuvettes into the receiving areas of their incubator within a common horizontal plane. On the other hand, the pusher blade assemblies of Applicant's incubator can permit loading and unloading as well as radial movement between slide element receiving areas. Moreover, the reciprocating pusher blade assemblies can be provided at different circumferential or radial locations. For example, at least one second drive mechanism having a reciprocating pusher blade assembly, can be provided in relation to the outer ring and at least one second drive mechanism, also having a corresponding reciprocating pusher blade assembly, can be provided in relation to the inner ring. Other variations are possible. For example, a plurality of pusher blade assemblies can be disposed at various circumferential locations about the outer ring to enable slide elements to be selectively loaded and/or moved between the inner and outer rings of the incubator as the rings are being rotated by at least one first drive mechanism.

Each of independent Claims 62 and 63 have been amended to clearly recite the above features. More particularly, Claim 62 has been amended to specify and more definitely point out and distinctly describe the use of at least two second drive mechanisms for selectively moving slide elements in a radial direction exclusively within a common horizontal plane. This permits slide elements to be loaded and

unloaded from the incubator and also permits movement of slide elements between first and second pluralities of slide element receiving areas. According to this claim, each of the second drive mechanisms includes at least one reciprocating pusher blade assembly for moving slide elements between the inner and outer rings of the incubator and for loading elements into at least one of the inner and outer ring. Support for these amendments is found in the present specification and drawings; see, for example, page 15, lines 1-22, and Figs. 10-12.

As noted above, Jakubowicz '633 fails to include any means for loading slide elements and moving slide elements between rings of an incubator.

Claim 63 has been amended to specify that radial loading and moving steps are performed in relation to an incubator structure and further within a common horizontal plane, exclusively, using slide elements and at least two reciprocating pusher blade assemblies that are disposed to effectuate these steps.

Because Jakubowicz '633 fails to describe or even suggest the foregoing features, it is believed that a statutory anticipation rejection of Claims 62 or 63 cannot be maintained. Reconsideration is therefore respectfully requested. Each of the remaining pending Claims 3, 6-22, 56-59 and 63-66 are also believed to be allowable for the same reasons in that these claims depend from Claims 62 and 63 and include additional features. Reconsideration is therefore respectfully requested.

With regard to the Section 103 rejection, Applicant herein respectfully traverses this rejection. In order to maintain a successful "*prima facie*" obviousness rejection under the Statute, each and every claimed limitation must be found in the cited prior art, either singly or in combination. Those limitations that are not found in or are suggested by the prior art must be notoriously well known in the field of the invention at the time thereof. To that end, there must be no impermissible hindsight (i.e., advance knowledge) of the invention.

As to the cited prior art, and as previously noted, Miller describes a twin rotor incubator assembly for a clinical analyzer. This incubator assembly includes a pair of independently driven, vertically stacked rotors 52, 54 that are interconnected by means of an elevator assembly relative to a metering station. The rotors are not

provided on a common horizontal plane. As slide elements are metered, the elements are brought into either of the vertically stacked rotors using a pusher blade assembly. In order to move any of the sample elements between these stacked and offset rings, however, there must be a vertical component of movement in order to access one of the rotors. That is to say, all movement is not exclusively made within a common horizontal plane. According to this reference and in order to move sample elements between the vertically stacked ring elements in order to "free up" space, for example, in one of the rings, a slide element must first be removed from one of the rings, loaded onto the elevator assembly, raised or lowered, and then reloaded horizontally into the remaining ring. That is to say, the sample element receiving areas of the first and second rotors are not provided on a common horizontal plane and therefore movement of slide elements between the slide element receiving areas of the rotors can not occur exclusively along a common horizontal plane. This reference fails to disclose a relationship between first and second pluralities of slide element receiving areas that would permit radial movement therebetween wherein slide elements are loaded and unloaded into the incubator and movement between inner and outer rings is accomplished exclusively and radially within a common horizontal plane.

Muszak et al. teaches the elevator assembly that is used by the Miller incubator. As such, this reference elevator fails to provide or suggest any structure or a resulting mechanism that permits or suggests radial transport exclusively along a common horizontal plane for loading slide elements into the incubator and movement between radially adjacent slide element receiving areas that are disposed on coplanarly arranged inner and outer rings.

Carey et al. describes an incubator assembly that is used to handle multiple assays in an immunoassay clinical analyzer. The incubator includes a housing having a single cuvette ring that includes a plurality of circumferential slots, each sized for receiving a cuvette. The cuvette ring is disposed above a magnet ring used in conjunction with a drive assembly 18 to drive the cuvette ring. The cuvette ring is driven radially so as to pass a plurality of circumferentially arranged stations,

including read stations. In addition, a number of other circumferentially disposed stations are positioned outside of the incubator housing as used to dispense reagents, wash fluids, and perform other assay reaction steps. The cuvettes are not moved to positions other than the cuvette ring during any read, aspirate or dispense operation utilizing the exterior disposed stations. This incubator also includes an elevator assembly, as described at col. 18, lines 56-67, wherein a cuvette can be lifted from a slot to permit a new cuvette to be added to take a now empty slot in the cuvette ring. This reference is vastly different from that of Claims 62, 63 for failing to teach, describe or otherwise suggest radially adjacent rings having slide element receiving areas wherein movement can be achieved exclusively between the rings and into the incubator along a common horizontal plane.

Finally, Hamilton et al. describes a slide distributor for the delivery and removal of slide elements from an incubator. See col. 1, lines 9-11. The slide distributor is defined by a single shuttle mechanism located outside of the incubator housing that can be used to either load or unload slide elements from an incubator. The shuttle mechanism includes a single pusher blade assembly having a picker to enable the slide elements to be loaded and/or unloaded from the single ring incubator.

As noted above, each of the independent Claims 62 and 63 have now been amended to specifically indicate that the incubator comprises at least two second drive mechanisms (reciprocating pusher blade assemblies) that enable radial movement either into and/or out of the incubator, as well as radial movement between the inner and outer rings. All movement is achieved along a common horizontal plane with regard to the slide elements as to the recited radial loading and radial moving steps. Support is found repletely in the present application, see, for example Figs. 10-12, and therefore it is believed that no new matter has been added.

To that end, it is believed that a "*prima facie*" obviousness rejection cannot be maintained based on the cited art. The combination of the cited art fails to provide the structure of the invention that is now positively recited in independent Claim 62. That is, none of the cited prior art, either singly or in combination,

provides an incubator having an inner and an outer ring wherein the inner ring includes a first plurality of circumferentially disposed slide element receiving areas and the inner ring includes a second plurality of slide element receiving areas. As previously noted, each of the primary references to Muszak et al. and Miller define first and second pluralities of slide element receiving areas, but in which the areas are not radially adjacent or at least in which movement cannot occur exclusively between the areas and into the incubator along a common horizontal plane. Hamilton refers to a single rotor incubator design while Carey describes an incubator that transfers cuvettes and does not include means for transferring or shuttling slide elements between rings exclusively on a common horizontal plane.

Moreover, none of the cited art alone or in combination, recites or suggests at least two reciprocating pusher blade assemblies that selectively moves slide elements exclusively in a radial direction along the horizontal plane common to the first and second plurality of slide element receiving areas, as well as in relation to apparatus disposed outside the incubator housing. Since Miller and Muszak et al. specifically require the rings be vertically stacked, the sample element receiving areas cannot be formed within a common horizontal plane as required by each of independent Claims 62 and 63. Carey and Hamilton each relate to single ring structures only. Moreover and as previously noted, Carey does not relate at all to the transfer of slide elements, but rather to cuvettes, whose design does not permit transfer successful and reliably if using reciprocating pusher blade assemblies. In addition and like Jakubowicz '633, it is believed that the cuvettes of Carey et al. cannot be loaded radially into the outer ring and therefore they must be loaded vertically. As such, exclusive radial movement is not possible as required by the claims. For the foregoing reasons, it is believed that a prima facie obviousness rejection cannot be made regarding Claims 62 and 63.

Each of Claims 3, 6-22, 56-59, and 64-66 are believed allowable since these claims depend from Claim 62 and 63. Reconsideration is respectfully requested.

Serial No.: 09/904,692
Amendment Dated: July 11, 2006
Reply to Office Action of April 14, 2006

Claims 3, 6, 7, 11, 15-20, 56, 58 and 64-66 have been amended to comport with the amendments made to Claims 62 and 63 and also to correct certain typographic and grammatical errata that was not previously detected. No new matter has been added.

In summary, it is believed the above-captioned patent application is now in an allowable condition and such allowance is earnestly solicited.

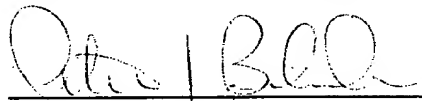
If the Examiner wishes to expedite disposition of the above-captioned patent application, he is invited to contact Applicants' representative at the telephone number below.

The Director is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0289.

Respectfully submitted,

WALL MARJAMA & BILINSKI LLP

By:



Peter J. Bilinski
Reg. No. 35,067

PJB/scp
Telephone: (315) 425-9000

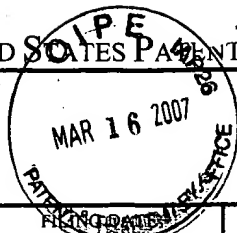
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09/904,692	07/13/2001	Raymond Francis Jakubowicz	961_002	4749

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EXAMINER

ALEXANDER, LYLE

ART UNIT PAPER NUMBER

1743

DATE MAILED: 09/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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10-2-06



Office Action Summary

Application No.

09/904,692

Applicant(s)

JAKUBOWICZ ET AL.

Examiner

Lyle A. Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,6-22,56-59 and 62-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,6-22, 56-59 and 62-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3,6-22, 56-59 and 62-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The 7/11/06 amendments specify "... at least two second drive mechanisms...." which is not taught in the original disclosure. Upon review of the specification, the Office notes that a third drive mechanism is taught. Is the claimed second "second drive mechanism" the same as the taught third drive mechanism. Applicants' response should direct the Office to the appropriate portions of the specification for support.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3,6-22, 56-59 and 62-66 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Jakubowicz et al. (USP 5,244,633).

Jakubowicz et al. teach an incubator using two independently driven concentric rings that have been read on the claimed "inner" and "outer" rings. The original

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specification of the instant application teaches of page 7 lines 8+ "... the term "element" ... refers to ... any form of sample container". The claimed "slide elements" have been read on the taught --cuvettes--. Claim 1 stated the two rings are in a common plane, independently rotated and that sample cuvettes are moved between the rings without coming out of the common horizontal plane.

Response to Arguments

Applicant's arguments filed 7/11/06 have been fully considered but they are not persuasive.

Applicants' amendments that specify the inner and outer rings rotate about an axis within a common horizontal plane and the slide elements move exclusively within the common plane were sufficient to overcome the 35 USC 103 rejections over Miller, Carey and Muzak et al.

Applicants' state Jakubowicz et al. are not relevant because they are directed to movement of "cuvettes" rather than "slide elements". The original specification of the instant application teaches of page 7 lines 8+ "... the term "element" ... refers to ... any form of sample container". The claimed "slide elements" have been properly read on the cuvettes taught by Jakubowicz et al. Applicants' may consider better defining the claimed "slide elements" to define over these references.

Applicants' state Jakubowicz et al. fail to teach loading of the cuvettes into the inner ring. The pending limitations do not exclude the movement of a sample from the outer ring to the inner ring which read on the instant claims. The pending claims do not

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specify loading of the inner ring from somewhere other than the outer ring. Rather, the claims are directed to relative movement between the rings which is met by Jakubowicz et al.

Applicants' state Jakubowicz et al. fails to teach the at least one second drive mechanism including at least one reciprocating pusher blade assembly for loading slide elements into said inner ring and for moving slide elements between said inner ring and said outer ring. Jakubowicz et al. teach pusher elements(204,208) that have been read on the instant claims.

Applicants' state Jakubowicz et al. teach a different type of pusher than presently claimed here. The instant claim language is sufficiently broad that it has been properly read on Jakubowicz et al.

Applicants' state claims 62-63 have been specifically amended describing the pusher blade assembly enabling radial movement either into and/or out of the incubator, as well as radial movement between the inner and out rings. It appears the instant claims are directed to the relative movement between the inner and out rings.

Applicants' may consider further amendments to better describe the movements of slides into or out of the incubator.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Lyle A Alexander
Primary Examiner
Art Unit 1743

